The circulatory–respiratory determination of death in organ donation*

James L. Bernat, MD; Alexander M. Capron, LLB; Thomas P. Bleck, MD; Sandralee Blosser, MD; Susan L. Bratton, MD, MPH; James F. Childress, PhD; Michael A. DeVita, MD; Gerard J. Fulda, MD; Cynthia J. Gries, MD, MSc; Mudit Mathur, MD; Thomas A. Nakagawa, MD; Cynda Hylton Rushton, PhD, RN; Sam D. Shemie, MD; Douglas B. White, MD, MAS

Objective: **Death statutes permit physicians to declare death on the basis of irreversible cessation of circulatory–respiratory or brain functions. The growing practice of organ donation after circulatory determination of death now requires physicians to exercise greater specificity in circulatory–respiratory death determination. We studied circulatory–respiratory death determination to clarify its concept, practice, and application to innovative circulatory determination of death protocols.**

Results: **It is ethically and legally appropriate to procure organs when permanent cessation (will not return) of circulation and respiration has occurred but before irreversible cessation (cannot return) has occurred because permanent cessation: 1) is an established medical practice standard for determining death; 2) is the meaning of "irreversible" in the Uniform Determination of Death Act; and 3) does not violate the "Dead Donor Rule."**

Conclusions: **The use of unmodified extracorporeal membrane oxygenation in the circulatory determination of death donor after death is declared should be abandoned because, by restoring brain circulation, it retroactively negates the previous death determination. Modifications of extracorporeal membrane oxygenation that avoid this problem by excluding brain circulation are contrived, invasive, and, if used, should require consent of surrogates. Heart donation in circulatory determination of death is acceptable if proper standards are followed to declare donor death after establishing the permanent cessation of circulation. Pending additional data on "auto-resuscitation," we recommend that all circulatory determination of death programs should utilize the prevailing standard of 2 to 5 mins of demonstrated mechanical asystole before declaring death. (Crit Care Med 2010; 38: 963–970)**

KEY WORDS: organ donation; circulatory death; cardiac death; dead donor rule; auto-resuscitation; extracorporeal membrane oxygenation

The determination of human death continues to provoke public fascination and medical scrutiny. In its 1981 report *Defining Death,* the U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research provided the most frequently cited comprehensive analysis (1). *Defining Death* had three principal goals: 1) to provide a conceptual basis for the new medical practice of death determination using neurological tests; 2) to explain the relationship between determining death on neurological and circulatory-respiratory grounds; and 3) to enhance the uniformity among jurisdictions by proposing and justifying a

***See also p. 1011.**

From the Neurology Department (JLB), Dartmouth-Hitchcock Medical Center, Lebanon, NH; Gould School of Law (AMC), Keck School of Medicine, Pacific Center for Health Policy and Ethics, University of Southern California, Los Angeles, CA; Department of Neurological Sciences (TPB), Rush University Medical Center, Chicago, IL; Adult Critical Care (SB), Penn State Hershey Medical Center, Hershey, PA; Department of Pediatrics (SLB), University of Utah Medical Center, Salt Lake City, UT; Department of Religious Studies (JFC), University of Virginia, Charlottesville, VA; Medical Affairs (MAD), West Penn Allegheny Health System, Pittsburgh, PA; Department of Surgical Critical Care (GJF), Christiana Care Health System, Newark, DE; Pulmonary and Critical Care Medicine (CJG), University of Washington, Seattle, WA; Pediatric Critical Care (MM), Loma Linda University Children's Hospital, Loma Linda, CA; Pediatric Critical Care Medicine (TAN), Wake Forest University School of Medicine, Brenner Children's Hospital, North Carolina Baptist Medical Center, Winston-Salem, NC; School of Nursing, Medicine, & Berman Institute of Bioethics (CHR), Johns Hopkins University, Baltimore, MD; Department of Critical Care Medicine (SDS), Montreal Children's Hospital, McGill University, Montreal, Quebec, Canada; Department of Critical Care Medicine (DBW), University of Pittsburgh Medical Center, Pittsburgh, PA

Dr. Childress has employment with the University of Virginia and has consulted for Aoche and Johnson and Johnson. Dr. Childress is also Chair for IOM Committee that produced Organ Donation = Opportunities for Action. The remaining authors have not disclosed any potential conflicts of interest.

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For information regarding this article, E-mail: bernat@dartmouth.edu

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model statute, the Uniform Determination of Death Act (UDDA).

The Commission relied on the *Guidelines for the Determination of Death* developed by an expert group of medical consultants to clarify accepted medical standards. The consultants provided specific guidance for physicians using neurological tests to determine death and devoted less attention to explaining how death should be determined based on the absence of circulation and respiration (2).

The increasing practice of organ donation after circulatory determination of death (DCDD) now makes it important to develop more detailed guidelines on how physicians should employ the circulatory-respiratory tests for death in patients who are potential organ donors. The growth of DCDD–also known as donation after cardiac death or nonheart-beating organ donation–has been spurred by the publication of three supporting reports by the Institute of Medicine (3–5), endorsement and encouragement by the U.S. Department of Health and Human Services through support of programs to increase DCDD such as the Health Resources and Services Administration Organ Donation Breakthrough Collaborative, and the recent establishment of quality criteria by the Joint Commission for hospitals engaged in DCDD (6).

Transplant programs in the United States and Canada use "controlled DCDD," in which donation is offered after a patient or surrogate has decided that life-sustaining therapy should be withdrawn and cardiopulmonary resuscitation withheld, and consent given for the removal of organs upon the patient's death. Most U.S. programs currently exclude organ donors unsuccessfully resuscitated from in or out-of-hospital cardiac arrest, though investigational pilot programs are underway of "uncontrolled DCDD" similar to those already in use in some European countries (7).

Every DCDD protocol requires that physicians conduct a "death watch" in which they measure the exact duration of circulation cessation and apnea, and declare death only when the time stipulated in the protocol has elapsed (8). Since the Uniform Anatomical Gift Act (adopted in all states) established what has been called the "Dead Donor Rule" (DDR), namely that donors of vital organs must be declared dead before organ removal rather than dying as a result of donation (9), the precise moment in DCDD protocols for declaring when death has occurred has become an important medical practice issue. However, the techniques of death determination and the required duration of cessation of circulation before death can be declared are based on meager data, lack standardization, and vary among hospitals (10).

As new DCDD protocols expanded the circumstances in which patients could become organ donors, initially some questioned whether they were consistent with the DDR. While these doubts have largely been resolved (3–6), recent efforts to extend the "boundaries" of DCDD by adding hearts to the list of organs that may be recovered or initiating invasive medical interventions to protect organs in the donor, have revived questions about whether the new protocols skirt relevant ethical or legal norms and other accepted principles of organ donation (11).

To re-examine the standards for death determination and to analyze the new protocols' compliance with these standards, an interdisciplinary panel was convened with support from the Health Resources and Services Administration Division of Transplantation, the agency providing funding for many DCDD investigational protocols. In this report of the panel, we rigorously analyze death determination using circulatory-respiratory tests and use these concepts to assess two recently developed controversial DCDD protocols: postmortem extracorporeal membrane oxygenation (ECMO) to support donor organs, and the transplantation of hearts. We acknowledge the limitations of our arguments, the tentativeness and controversial nature of our recommendations, the need for further research, and the desirability of continued ethical analysis and assessment.

Death Determination using Circulatory-Respiratory Tests

Nearly every state has enacted the UDDA, the model statute proposed in 1981 by the President's Commission, or a substantially similar statute (12).

The UDDA provides: "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards" (1).

In *Defining Death* (1), the President's Commission held that these two standards are alternative means of determining that a human being has died. The statute sets forth both standards because "the accepted standard for determining death [which] has been the permanent absence of respiration and circulation" will continue to be used in most death determinations. However, because a "question arises about continued reliance on the traditional standard because advances in medical technique now permit physicians to generate breathing and heartbeat when the capacity to breathe spontaneously has been irretrievably lost," it was necessary also to establish the irreversible cessation of brain functions as an alternative means of determining that death has occurred.

Although stated separately, the two standards are essentially a single one based on brain functions. If, through timely cardiopulmonary resuscitation or other mechanical or pharmacologic support, circulation and respiration are restored in the relatively brief period before all brain functions are destroyed by the lack of oxygenated blood, the patient would not be dead. Cessation of circulation and respiration can be viewed as a valid means for establishing cessation of brain functioning—and hence death—both because unsupported patients without any brain functions lack spontaneous breathing and hence cardiac activity, and because cessation of brain functions follow quickly after the loss of circulatory and respiratory functions in the absence of medical intervention.

The use of the term "irreversible" cessation of functions in the UDDA to demarcate when death has occurred has led many observers to assume that irreversibility sets an unequivocal legal standard of death. The UDDA does not itself define the term "irreversible." Guidance in interpreting the term can be found, however, in *Defining Death* (1), which serves as the principal piece of legislative history for the UDDA in the absence of reports or remarks in state legislatures addressing the term. In *Defining Death* (1), "irreversible" is used interchangeably with "permanent" because both words designate a condition that is stable and unchanging. The difference between them relates not to the certainty or duration of the cessation of relevant functions but rather to the implication in "irreversible" that an external actor or force is present that could attempt to restore the function but would be unable to do so.

An "irreversible" cessation of function means that the function cannot be re-

stored by any known technology. "Irreversible" is an absolute and univocal condition that implies impossibility (with currently available technology) and does not rely on intent or action. In contrast, a "permanent" cessation of function means that the function will not be restored because it will neither return spontaneously, nor will return as a result of medical intervention because resuscitation efforts will not be attempted. In this analysis, "permanent" is a contingent and equivocal condition that admits possibility and relies on intent and action to be realized.

The two terms are distinct but causally related in two ways. All functions that are irreversibly lost are also permanently lost (but not vice versa). A condition might be declared permanent but only if an attempt were made to reverse it (and failed) could one know whether the loss is irreversible. Furthermore, in the context of death determinations uncomplicated by resuscitative technology, all functions that are permanently lost quickly and inevitably become irreversibly lost, so permanent cessation serves as a valid stand-in for irreversible cessation (13).

In determining whether an individual met the statutory standard of "irreversible cessation of circulatory and respiratory functions," the President's Commission's medical consultants provided specific guidance on the meaning of "cessation" and "irreversible." Cessation "is recognized by an appropriate clinical examination" that discloses "at least the absence of responsiveness, heartbeat, and respiratory effort," whereas irreversibility "is recognized by persistent cessation of functions during an appropriate period of observation and/or trial of therapy." (2) The consultants' Guidelines elaborated on the "appropriate period of observation" as follows.

In clinical situations in which death is expected, in which the course has been gradual, and in which irregular agonal respiration or heartbeat finally ceases, the period of observation following the cessation may be only the few minutes required to complete the examination. Similarly, if resuscitation is not undertaken and ventricular fibrillation and standstill develop in a monitored patient, the required period of observation thereafter may be as short as a few minutes. When a possible death is unobserved, unexpected, or sudden, the examination may need to be more detailed and repeated over a longer period, while appropriate resuscitative effort is maintained as a test of cardiovascular responsiveness. Diagnosis in individuals who are first observed with rigor mortis or putrefaction may require only the observation period necessary to establish that fact (2).

When cardiopulmonary resuscitation is not performed, the statutory requirement—which the medical consultants described as a "persistent cessation of functions"—is met by the relatively brief period of observation after asystole that is sufficient to determine that the loss of spontaneous heartbeat and respiration is permanent. When cardiopulmonary resuscitation is performed, a longer period may be required before one concludes that the loss of circulation and respiration cannot be reversed. The period of observation before death can be declared is intended to assure that the patient's circulatory and respiratory functions have ceased permanently. The President's Commission saw the end point as permanence. Proof of irreversibility was required only if medical efforts were made to attempt to reverse the loss of functions, that is, irreversibility was proved when resuscitative efforts had failed.

After a determination of permanent cessation of circulatory and respiratory functions (assuming normothermia and an absence of depressant medications that could reduce cerebral metabolism and lengthen the process), as the patient's brain becomes completely destroyed by hypoxic–ischemic injury, the cessation will evolve from permanent to irreversible. The exact timing of this transition is unknown and usually moot because no attempt is made to resuscitate or further assess the patient.

Although some physicians in the 18th and 19th centuries advocated awaiting such advanced signs of death as rigor mortis or putrefaction before making a declaration (14), contemporary physicians try to make the determination of death as soon as it is medically clear. The guidelines set forth in the 1981 medical consultants' report, which recognize permanent cessation as the relevant standard in patients not undergoing a trial of resuscitation, are reflected in physicians' customary practices for determining death based on circulatory–respiratory tests. These tests have been unquestionably accepted by society and represent medical standards.

The following examples illustrate the use of "accepted medical standards" in determining death. When called to the bedside to declare the death of a hospitalized patient with widely metastatic carcinoma who was receiving palliative care, had a do not resuscitate order, and was expected to die, a physician would ascertain cessation of circulation and respiration and declare the patient dead because auto-resuscitation does not occur in this setting and medical resuscitation will not be attempted. An ICU patient in whom develops intractable asystole develops while being carefully monitored by electrocardiogram and arterial line pressures would be declared dead when cardiac rhythm showed constant asystole. A person receiving cardiopulmonary resuscitation for cardiac arrest would be declared dead once the medical team deems the resuscitation unsuccessful. In each of these applications of the circulation–respiration tests of death, physicians declare death at the point that the cessation of circulation and respiration can be diagnosed as permanent; they do not undertake any direct measuring of brain functions, much less await the total brain infarction that establishes that the loss of circulation and respiration could not be reversed.

SUBJECTS AND METHODS

Death Determination in the Circulatory Determination of Death Donor

We now apply these concepts to determining death in the DCDD donor patient. After 2 to 5 mins of cessation of breathing and circulation, it is clear that the donor's circulatory and respiratory functions have ceased permanently. Studies have shown that patients in this setting do not spontaneously recover circulation or breathing ("auto-resuscitate") after 65 seconds of asystole (8, 15). It is inherent in DCDD that donor patients will not receive cardiopulmonary resuscitation because it is the choice of the patient or surrogate to allow natural death to occur by withdrawal of life-sustaining therapy in a manner that enables the donation of organs. In the absence of auto-resuscitation or cardiopulmonary resuscitation, the DCDD donor patient's circulatory and respiratory functions have ceased permanently.

Is permanent cessation of circulatory and respiratory functions a valid proxy for their irreversible cessation in the DCDD donor patient, or does the act of organ donation interrupt or accelerate the donor's rapid and inevitable transition from permanent to irreversible cessation? In fact, the removal of donor organs has no impact whatsoever on the

process of progressive hypoxic–ischemic brain destruction that when completed is the hallmark of irreversibility (16). Once circulation has ceased permanently, the same brain destruction occurs whether the organs remain present or have been removed. Although there is a clear difference in the context and consequentiality of death determination in DCDD when compared to other circumstances, there is no physiologic difference in the inevitable sequence from permanence to irreversibility. Therefore, using the criterion of permanence produces no difference in donor outcome from using irreversibility (13).

Physicians should apply circulatory–respiratory testing for death in a consistent way, irrespective of whether the patient is an organ donor candidate, but they should exercise greater precision in determining the moment and totality of permanent cessation of circulation in the DCDD circumstance, because of its consequentiality. The advent of DCDD has simply highlighted the need for physicians to make death determination more uniformly and reliably.

Does physicians' use of the permanence criterion to declare death in DCDD violate the DDR as some scholars have claimed? We conclude that it respects the DDR because it fully satisfies the requirements of the UDDA by reflecting "accepted medical standards." The manner in which permanent cessation of circulation and respiration is used to determine death in DCDD is completely consistent with physician's use of this standard in all other contexts in which circulation and respiration are measured. Whereas we recognize that proving the moment of permanence usually is not consequential in non-donor patients, DCDD creates an exceptional circumstance in which it is essential for physicians to determine the exact timing and methods to prove permanence.

Medical Considerations in Determining Death

It is useful to clarify several relevant medical issues. The condition "asystole" (absent heartbeat), an essential concept in DCDD protocols, can create terminological confusion. Mechanical asystole signifies the absence of arterial pulsations, which can be absent even when a coordinated electrical cardiac rhythm persists. Electromechanical asystole means the absence of both electrical and mechanical cardiac activity. For death determination, there is a consensus that mechanical asystole is sufficient and electrical asystole is unnecessary because the standard for declaring death requires absence of circulation, not absence of cardiac electrical function (17). Pulseless electrical cardiac activity (mechanical asystole) that generates no circulation therefore is inconsequential in a death determination. If tests demonstrate electrical asystole, then that alone is sufficient to prove mechanical asystole because neither heartbeat nor circulation can occur during electrical asystole in the absence of external cardiac or circulatory support.

Physicians can assess asystole by several techniques. Traditionally, physicians have determined mechanical asystole by palpating arterial pulses or listening for heartbeat. These techniques usually are adequate in ordinary circulatory–respiratory death determinations in the hospital and elsewhere. In the DCDD donor patient for whom the determination is more consequential, however, these usual means may be inadequate to distinguish a complete loss of circulation from a slight degree of retained circulation that is insufficient to generate a palpable pulse or an audible heartbeat. To prevent errors in death determination, physicians in many medical centers conducting DCDD routinely monitor circulation using an indwelling arterial catheter that sensitively and specifically measures arterial pulsations and pressures. Some physicians perform percutaneous Doppler ultrasound on peripheral arteries or echocardiography to show no blood flow through the aortic valve, and most also monitor cardiac electrical rhythm.

Patients who die after cessation of circulation and respiration can experience cardiac arrest followed immediately by respiratory arrest or respiratory arrest followed by cardiac arrest. In the typical setting of DCDD, the donor patient is ventilator-dependent, usually as a result of brain damage that interferes with normal ventilatory drive and airway maintenance. After the decision that life-sustaining treatment should be withdrawn, and subsequently consent for organ donation has been requested and secured, and the evaluation for donation completed, critical care physicians caring for the patient either extubate or rapidly wean the patient from the ventilator. They prescribe opioid and benzodiazepine medications that would be appropriate for palliative purposes in this setting irrespective of organ donor status (18). The usual sequence of loss of vital functions leading to the death of the DCDD patient is respiratory arrest followed by cardiac arrest. Once asystole occurs, the duration of mechanical asystole is carefully measured before death is declared (8).

The duration of mechanical asystole required to prove permanent cessation of circulation has been the subject of study and speculation. The protocol at the University of Pittsburgh Medical Center (19), a pioneer in DCDD, continues to specify a 2-min duration based on the rationale that 65 seconds is the longest recorded interval of observed asystole followed by auto-resuscitation (15). Yet, because the observational studies of auto-resuscitation comprised relatively few patients and the resultant statistical confidence interval is modest, it is possible that future cases could occur after >65 seconds of mechanical asystole. The Institute of Medicine has therefore recommended a more conservative 5-min interval, which has been adopted by the majority of United States DCDD programs (5). After a critical review of the auto-resuscitation data, the Ethics Committee of the Society of Critical Care Medicine suggested a minimum of 2 mins and a maximum of 5 mins for the observation period (20). Pending the collection of further data on auto-resuscitation, this prudent conclusion was endorsed by leaders of the DCDD community at the 2005 National Conference on Organ Donation after Cardiac Death (17). A recent study of auto-resuscitation after withdrawal of life-sustaining therapy found reports of returned cardiac rhythm but none of returned circulation (Hornby K, Hornby L, Shemie SD, unpublished, 2009).

Because of the need to assess the exact duration of asystole to determine death in the DCDD patient, it is essential to prove mechanical asystole. Although pulse palpation and cardiac auscultation are insufficiently sensitive techniques, complete cessation of circulation can be demonstrated by the absence of pulsations detected by an arterial catheter, the absence of pulsatile flow shown by percutaneous Doppler ultrasound, or the absence of intracardiac blood flow on echocardiography. When cessation of cardiac electrical activity is shown by electrocardiography, mechanical asystole is also established, but such tests are unnecessary. Residual pulseless electrical cardiac activity may continue for many minutes despite complete mechanical asystole proved by blood flow measurements (21). Now we apply these concepts to two controversial DCDD protocols: the use of ECMO to support donor organs and the recovery of donor hearts.

ECMO Support of Circulatory Determination of Death Donors

ECMO is a technique that was developed as a bridge to support cardiorespiratory functions in patients with severe heart or lung dysfunction pending receipt of a transplanted heart (22), lungs (23), or heart and lungs, and later used as an adjunct to failed cardiopulmonary resuscitation (24), and in prolonged inhospital cardiac arrest (25). Veno-arterial ECMO shares many features in common with a typical heart–lung machine used to oxygenate and circulate blood during open-heart surgery with induced asystole, but ECMO is designed to replace cardiopulmonary functions for days or a few weeks rather than for hours.

Controversy has arisen, however, after surgeons at several transplantation cen-

ters reported their preliminary experiences using ECMO for maintaining organ function in the DCDD donor after the declaration of death but before organ recovery (26–30). These protocols introduce ECMO support immediately after death declaration through arterial and venous catheters inserted before death is declared. ECMO improved outcomes in transplanted kidney, livers, and pancreases from DCDD donors because of improved organ perfusion and oxygenation before organ recovery. By maintaining the flow of oxygenated blood to the organs to the moment of recovery and thereby reducing warm ischemic time, ECMO improved the viability of donor organ function in a way similar to organs recovered from a brain-dead donor with a beating heart. This improvement in recovered organs permitted an expansion of the potential organ donor pool by 33% at one institution (29).

However, the use of ECMO in the DCDD donor creates a problem with death determination because it retroactively negates the physiologic justification for declaring the DCDD donor dead. By allowing reperfusion of the brain and thereby preventing brain destruction, it interrupts the otherwise inevitable progression from permanent loss of circulation and respiration to irreversible loss. Restoring brain circulation also raises the possibility of retaining donor consciousness and the consequent potential for suffering.

DCDD organ donors who are not supported by ECMO can be reliably declared dead after 2 to 5 mins of asystole because the permanent cessation of circulation is a valid means of establishing irreversible cessation. However, the use of ECMO interrupts the otherwise inevitable progression to brain destruction because donor circulation and oxygenation are restored. As an ongoing means of cardiopulmonary support, ECMO prevents the donor from being declared dead using circulatory–respiratory tests of death.

The same support of oxygenation and circulation by ECMO that is effective for visceral organ support also provides brain support. The reason that the irreversible loss of respiration and circulation serves as an adequate test of death is because it inevitably leads to destruction of the brain (31). If otherwise inevitable progressive brain destruction is prevented by restoring brain circulation using ECMO, the donor patient cannot reliably be declared dead before organ recovery, a circumstance that clearly violates the DDR.

Investigators at the University of Michigan (28, 29) and elsewhere (27) have modified whole-body donor ECMO in such a way that, if applied successfully, apparently eliminates this problem and therefore may represent a technically acceptable protocol. Before death is determined and when the arterial and venous ECMO catheters are inserted, a deflated intra-aortic occlusion balloon is also placed in the distal thoracic aorta at the level of the diaphragm. At the moment death is declared and ECMO is initiated, the aortic balloon is inflated thereby blocking all ECMO-produced aortic blood flow superior to the diaphragm.

The modified donor ECMO oxygenation–perfusion circuit includes abdominal and pelvic organs that are perfused by the infradiaphragmatic aorta but excludes thoracic organs and the brain. If the aorta is completely occluded, then the brain will undergo the same ischemic infarction that would have occurred without ECMO. Because brain destruction occurs in the modified ECMO-supported donor, this intervention does not retroactively negate the determination of the donor's death. Proof of absent brain circulation is necessary but is not routinely performed by surgeons using modified ECMO support. Alternative techniques that successfully exclude brain circulation during ECMO, such as bilateral carotid and vertebral artery ligation or infusing clear prime solutions that do not result in establishing oxygenation and circulation, also can accomplish the goal of not interfering with progressive brain destruction and negating death determination.

However, the techniques that modify ECMO by preventing brain circulation are disturbingly invasive. Interventions before and after death is declared raise ethical issues and some commentators have described these techniques as unjustifiably invasive and have wondered if performing them serves only to satisfy the letter of the UDDA while violating its spirit (32, 33). If these techniques are used, additional testing to prove the complete absence of intracranial circulation will be necessary, adding further invasive monitoring of the donor. Pre-mortem invasive procedures that aim to improve organ preservation but that do not help the donor also are objectionable and may distract the health care team's focus from its goal of maintaining optimal palliative care for the patient during withdrawal of life support (32). At the least, families of DCDD donors must be informed about the procedures that accompany DCDD and, if they object to them, must be allowed to decline DCDD so that the death is managed differently.

An uncontroversial and perhaps more preferable use of ECMO support in organ transplantation is to perfuse and oxygenate organs after they have been removed from the body. This procedure, called *ex vivo* ECMO, has been reported to enhance successful multi-organ donation in DCDD (34). *Ex vivo* ECMO offers three advantages over donor ECMO: 1) it does not interfere retroactively with the determination of donor death; 2) it does not require inserting catheters into the donor before the declaration of death; and 3) it does not require invasive modifications, such as intra-aortic balloon occlusion, to make it acceptable. *Ex vivo* ECMO offers a noninvasive, preferable alternative to modified donor ECMO and maintains trustworthiness of the donation process.

Heart Donation in Circulatory Determination of Death

A recent report of three successful infant DCDD heart donations ignited a firestorm of controversy about whether the infant donors were truly dead at the moment of organ recovery. Boucek et al (35) reported a Health Resources and Services Administration-sponsored experimental DCDD protocol in which hearts recovered from three infants with profound brain damage (but not brain death) were transplanted successfully into three infants with end-stage heart disease. In two cases, the investigators reduced to just 75 seconds the 3-min period of asystole required by the experimental protocol before death was declared. This *ad hoc* reduction was based on the recommendation of the hospital's ethics committee to reduce the risk of injury to the transplanted heart from warm ischemia.

Although the investigators (36) were congratulated on their technological virtuosity and the successful rescue of three doomed babies, critics focused on two questions. First, were physicians (11) justified in shortening the prevailing 2- to 5-min interval of asystole required to determine death? Infants were not included in the patient database on autoresuscitation from which this guideline was derived and infants' organs are known to be more resilient than adults' organs. The

response to this question is essentially prudential: practice standards are intentionally conservative to maintain public confidence in the accuracy of death determination by eliminating the possibility of false-positive diagnoses, a problem that is plausible given the modest numbers of patients comprising the database on auto-resuscitation.

Second, did successfully restarting the donor infants' hearts in the recipient infants retroactively negate the determination of "cardiac death" in the donor infants by clearly demonstrating that their heart stoppage was not irreversible? This is a more serious conceptual attack whose analysis requires an understanding of the nature of circulatory–respiratory death determination. In one commentary, Annas (37) criticized the DCDD heart recovery protocol, stating that transplanting and restarting the heart was illegal because it clearly violated the UDDA requirement for irreversibility of heart function. However, as we have shown, "accepted medical standards" establish the permanent cessation of circulation and respiration as the basis for declaring death of patients—donors or otherwise—when no efforts are made to reverse that cessation. In another commentary, Veatch (38) asserted: "if a heart is restarted, the person from whom it was taken cannot have been dead according to cardiac criteria." Such critiques might be quite telling if they did not misread the statutory standard for determining death.

The standard of death stipulated in the UDDA is "irreversible cessation of circulatory and respiratory functions." The first part of the standard often is misinterpreted as cessation of heartbeat because the heart is the organ ordinarily responsible for circulation, and because the absence of heartbeat is a customary sign of the absence of circulation. But circulation, not heartbeat, is the critical function that must be absent when using circulatory–respiratory tests to determine death. For example, we do not declare patients dead on the grounds of absent heartbeat who are on ECMO awaiting heart transplantation (even if they never receive a heart) or supported by ventricular assist devices so long as their circulation remains continuously maintained.

"Cardiac death" is an erroneous interpretation of both the concept of death and the UDDA. When cardiopulmonary resuscitation will not be attempted, patients can be declared dead once heartbeat (and hence circulation) stops beyond the point that auto-resuscitation occurs. Whether the non-beating heart subsequently is left alone, removed and not restarted, or removed and restarted in another patient is irrelevant to the circulatory status of the dead patient. In DCDD, the removal and restarting of the heart elsewhere simply has no impact on the previous determination of the donor's death because the donor patient remains permanently without circulation in exactly the same way as if his non-beating heart had been left in place. Therefore, restarting the heart in another patient does not retroactively negate the determination of the donor's death.

A source of confusion on this point is the common but incorrect use of the phrase "donation after cardiac death," which misleadingly implies that circulatory death determination is solely the product of heartbeat cessation. The names we apply to activities or conditions often determine how we conceptualize them. The poor choice of a name, as exemplified most notoriously by the infelicitous term "brain death," can create profound and enduring misunderstanding. For reasons of conceptual clarity and accuracy, we urge that the acronym DCDD (or DCD) be restricted to signifying "donation after circulatory determination of death" and to abandon the use of "donation after cardiac death" and "donation after cardiac determination of death." Using DCDD to signify "donation after circulatory determination of death" is conceptually accurate because the UDDA requires the irreversible cessation of circulation, not heartbeat. As advised by the Institute of Medicine, the use of the acronym "DCDD" is consistent with the terminology used for organ donation after neurologic determination of death (39).

Circulatory Determination of Death and the Dead Donor Rule

Our analysis shows that death determinations under DCDD protocols follow the same standards and procedures used for other patients who die without cardiopulmonary resuscitation attempts; hence, organs recovered under these protocols comply with the DDR. Yet, Truog et al (40) have argued that it should not be necessary to establish a donor's death in compliance with the DDR. They claim that the distinction between permanent and irreversible loss of functions is a linguistic legerdemain given the ambiguities inherent in death determination that have been made explicit by the practice of DCDD (40). They argue that the DDR is routinely violated in DCDD, has outlived its usefulness, and has become counterproductive. Their proposed solution is simply to abandon the DDR and instead to rely solely on donations from incipiently dying patients who consent to have their organs removed before they die (41–43).

We have shown, however, that physicians' traditional and current application of the circulation–respiration tests of death rely on permanent cessation. This practice complies with the requirements of the UDDA, as was made apparent by the guidelines of the medical consultants on which the President's Commission relied. The accuracy and social desirability of physicians basing death determinations on tests of circulation and respiration are unquestioned. Therefore, determining death in DCDD donors using the most exacting and carefully applied versions of such tests meets prevailing medical practice and legal standards and fully satisfies the DDR.

Furthermore, abandoning the DDR would be undesirable because it would create a new set of problems, especially by jeopardizing public confidence in organ donation (44). The success of organ transplantation as a social practice depends on general acceptance that physicians can accurately and reliably determine death, and on patients being sure that surgeons will not remove their vital organs until after they die. Although some patients and families probably would continue to donate organs without a DDR, its elimination would create justifiable fear of abuses by physicians or family members and loss of confidence in the system. In sum, departing from the DDR is neither necessary nor prudent. Others who have recently studied this issue, including a national multidisciplinary DCDD consensus panel in Canada (45) and the U.S. President's Council on Bioethics (46), agree that the DDR should be maintained.

Physicians need to achieve uniformity in death determination practices. It is undesirable for physicians at different hospitals to use different standards to declare death. Medical societies should work to establish a uniform medical standard for the circulatory–respiratory determination of death that should be

adopted by all DCDD programs, as also has been urged for death determination using neurologic tests (47). These practices should be integrated into quality standards for end-of-life care (7).

CONCLUSIONS

We acknowledge the scientific limitations of any medical attempt to determine the moment of death and the important role of society in formulating rules governing death practices. We make these recommendations humbly with understanding that they remain controversial and that they may change with further research and ethical analysis.

First, to promote clarity, the abbreviation DCDD or DCD should refer to organ donation after circulatory determination of death, not organ donation after cardiac death. Death determination is based on the cessation of circulatory and respiratory, not cardiac, functions.

Second, physicians declaring death using circulatory–respiratory tests, whether the patient is a potential donor, can continue to rely on the prevailing standard of permanent cessation of circulatory and respiratory functions, when no medical intervention will be used that could interfere with the otherwise inevitable and rapid progression to ischemic brain infarction.

Third, correctly performed determinations of death under a DCDD protocol respect the dead donor rule.

Fourth, the assessment of and required interval for absent circulation and apnea before death is declared in a DCDD donor have empirical, medical, and prudential elements. Physicians should routinely conduct sensitive pulse assessment with arterial catheters or Doppler ultrasound, or echocardiographic measurement of aortic valve opening to confirm the total absence of circulation. The interval must be long enough to reasonably exclude the possibility of auto-resuscitation. Because the auto-resuscitation database is small and contains no infants or young children, it is prudent to choose an interval that assures a reasonably robust confidence interval. A duration of verified absent circulation of 2 to 5 mins should be used until more information about auto-resuscitation is known.

Fifth, after death has been declared, no medical intervention that re-establishes brain circulation (such as ECMO, cardiac compressions, or other elements of cardiopulmonary resuscitation) should be permitted on a DCDD donor because, by interfering with the otherwise inevitable progression to brain infarction, the use of such interventions retroactively negates the death determination.

Sixth, in organ donors perfused by veno-arterial ECMO, techniques to exclude brain circulation, such as intra-aortic balloon occlusion, carotid artery ligation, or clear prime solution infusion, may avoid negating a previous death determination and creating the potential of donor suffering but are undesirable because they are disproportionately invasive and may jeopardize the trustworthiness of the donation process. If they are used, then they require the consent of a surrogate decision maker. *Ex vivo* organ ECMO offers a preferable alternative means of enhancing organ recovery.

Seventh, recovering hearts from DCDD donors for transplantation is acceptable once death is declared by establishing the permanent cessation of circulation and respiration in the donor patient using accepted standards of assessment.

Eighth, it is desirable to promote uniformity of practice using the circulatory–respiratory tests of death, including their incorporation into DCDD protocols in different hospitals. Medical specialty societies should agree on uniform standards for death determination.

Ninth, as new protocols to expand the donor pool are implemented, procedural and ethical safeguards also should be implemented (such as the use of a designated donor advocate and routine ethics committee review) to increase the trustworthiness of the donation process for patients, families, and clinicians.

Last, additional research is needed in several areas: 1) the natural history of auto-resuscitation in different patient groups; 2) the impact of ECMO and chest compressions on the timing of death determination; 3) the impact of technological methods to confirm the absence of circulation; 4) the chronology of brain destruction after complete cessation of circulation; 5) public, family member, and professional attitudes and perceptions about invasive procedures on donors before and after death is declared; 6) whether family members see an important distinction between physicians using permanence and irreversibility in determining death; and 7) death determination in uncontrolled DCDD protocols.

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