

American Thoracic Society Documents



An Official American Thoracic Society/International Society for Heart and Lung Transplantation/Society of Critical Care Medicine/Association of Organ and Procurement Organizations/United Network of Organ Sharing Statement: Ethical and Policy Considerations in Organ Donation after Circulatory Determination of Death

Cynthia J. Gries, Douglas B. White, Robert D. Truog, James DuBois, Carmen C. Cosio, Sonny Dhanani, Kevin M. Chan, Paul Corris, John Dark, Gerald Fulda, Alexandra K. Glazier, Robert Higgins, Robert Love, David P. Mason, Thomas A. Nakagawa, Ron Shapiro, Sam Shemie, Mary Fran Tracy, John M. Travallie, Maryam Valapour, Lori West, David Zaas, and Scott D. Halpern; on behalf of the American Thoracic Society Health Policy Committee

THIS OFFICIAL STATEMENT WAS APPROVED BY THE AMERICAN THORACIC SOCIETY (ATS), JULY 2012; THE INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION (ISHLT), AUGUST 2012; THE SOCIETY OF CRITICAL CARE MEDICINE (SCCM), AUGUST 2012; THE ASSOCIATION OF ORGAN AND PROCUREMENT ORGANIZATIONS (AOPO), AUGUST 2012; AND THE UNITED NETWORK OF ORGAN SHARING (UNOS), SEPTEMBER 2012

CONTENTS

Executive Summary

Introduction

Methods

Results

Underlying Ethical Principles

Consent Process

Interventions

Declaration of Death

DCDD and the Provision of End-of-Life Care

Pediatric DCDD

Future Research Directions

Conclusions

Rationale: Donation after circulatory determination of death (DCDD) has the potential to increase the number of organs available for transplantation. Because consent and management of potential donors must occur before death, DCDD raises unique ethical and policy issues. **Objectives:** To develop an ethics and health policy statement on adult and pediatric DCDD relevant to critical care and transplantation stakeholders.

Methods: A multidisciplinary panel of stakeholders was convened to develop an ethics and health policy statement. The panel consisted of representatives from the American Thoracic Society, Society of Critical Care Medicine, International Society for Heart and Lung Transplantation, Association of Organ Procurement Organizations, and the United Network of Organ Sharing. The panel reviewed the literature, discussed important ethics and health policy considerations, and developed a guiding framework for decision making by stakeholders.

Supported by the American Thoracic Society and International Society for Heart and Lung Transplantation.

This document has an online supplement, which is accessible from this issue's table of contents at www.atsjournals.org

Am J Respir Crit Care Med Vol 188, Iss. 1, pp 103–109, Jul 1, 2013

Copyright © 2013 by the American Thoracic Society

DOI: 10.1164/rccm.201304-0714ST

Internet address: www.atsjournals.org

Results: A framework to guide ethics and health policy statement was established, which addressed the consent process, *pre-* and *post mortem* interventions, the determination of death, provisions of end-of-life care, and pediatric DCDD.

Conclusions: The information presented in this Statement is based on the current evidence, experience, and clinical rationale. New clinical research and the development and dissemination of new technologies will eventually necessitate an update of this Statement.

Keywords: organ donor; transplant; cardiac death; clinical ethics; transplant policy

EXECUTIVE SUMMARY

This statement is designed to provide a framework to guide ethics and health policy considerations in adult and pediatric controlled donation after circulatory determination of death (DCDD) from the perspective of critical care medicine and the transplant subspecialties. This report addresses controlled DCDD. Although uncontrolled DCDD, or donation after an unexpected circulatory arrest, also raises many ethical issues, it is beyond the scope of this statement. We provide ethics and policy considerations on five aspects of controlled DCDD:

1. Consent
 - a. When patients themselves have consented to organ donation, hospital critical care and organ procurement organization (OPO) representatives should respect the patient's donation decision and provide this information to surrogate decision makers.
 - b. After clinicians lead discussions with patients or surrogates about the decisions to withdraw life-sustaining therapies, discussions about DCDD should proceed promptly and be coordinated jointly by clinicians and OPO representatives.
 - c. Consent for DCDD should be obtained by individuals with appropriate experience and training; these individuals' organizational affiliations should always be disclosed clearly.

2. Interventions

- a. Use of *ante mortem* interventions and medications should be disclosed to surrogates at the time of consent and identified as being administered solely for the purpose of organ donation. Separate consent might be required for some *ante mortem* interventions consistent with hospital policies or state/local laws and regulations.
- b. *Ante mortem* interventions are ethically appropriate if they contribute to good transplant outcomes and have a low chance of harming the prospective donor.
- c. *Post mortem* donor management interventions such as extracorporeal membrane oxygenation that may stimulate physiologic functions (i.e., cardiac or brain function) require further analysis to determine their clinical usefulness and ethical merit.

3. Determination of death

- a. Death can be declared after the cessation of circulation and respiratory function for 2 minutes.
- b. Information about how death will be determined should be provided to the patient or the surrogates.

4. End-of-life care

- a. Surrogates should be informed during the consent process regarding: (1) how and where life-sustaining therapies will be withdrawn, (2) the amount of time they can spend with their loved one *post mortem*, and (3) the possibility that the patient may not die within the time interval necessary for DCDD to occur.
- b. Hospitals that participate in DCDD should ensure that experienced personnel with competency in palliative care are available to participate in end-of-life care if needed.
- c. Hospitals that participate in DCDD should have a clear policy regarding how and where patients will be cared for if they do not expire within the time interval acceptable for donation.

5. Pediatric DCDD

- a. Although pediatric patients (under the age of 18 yr) cannot provide consent to their own donation, consent of the parent or of another legal surrogate can be used.
- b. The ethical principles related to consent, intervention, declaration of death, and end-of-life care in pediatric DCDD patients is similar to those for adults.

INTRODUCTION

With more than 21,000 deceased donor transplants performed in the United States each year, transplantation has emerged as an established intervention for patients with advanced organ disease (1). Based on the Organ Procurement Transplantation Network data as of April 15, 2011, 26% of listed solid organ transplant candidates were too sick to be transplanted or died while awaiting transplant. Because the supply of "traditional" donors after neurological determination of death is insufficient to provide organs for all patients who might benefit from transplants (2, 3), other sources of organ recovery are being actively explored. The Institute of Medicine's review of current options available for obtaining additional transplantable organs has concluded that donation after circulatory determination of death (DCDD; formerly known as non-heart-beating organ donation or donation after cardiac death) is one of the most promising available options (4). Although the potential supply of DCDD

donors would not be sufficient to eliminate the organ shortage, it does offer the potential to increase the number of deceased donor transplants by roughly 10% annually (5).

Controlled DCDD entails the recovery of organs after cessation of circulation among patients with severe neurological, neuromuscular, or pulmonary disease for whom decisions are made to forego further life-prolonging treatments. DCDD organs from such donors account for increasing proportions of solid-organ transplants in the United States and elsewhere (6). Although DCDD may promote fulfillment of patients' intent to donate organs, DCDD raises unique ethical and medical considerations because: (1) consent for donation is always obtained before the declaration of death, and (2) several aspects of donor management geared toward ensuring organ viability must occur simultaneously with the provision of end-of-life care to dying patients.

Because the goal of recovering viable organs must occur together with maximum respect for the dying patient, a framework is needed to help establish DCDD protocols that mitigate these conflicts. To meet these needs, the American Thoracic Society Health Policy Committee developed this statement about the ethical and health policy considerations in DCDD, with representation from other critical care and transplant societies, including: Society of Critical Care Medicine, International Society for Heart and Lung Transplantation, Association of Organ Procurement Organizations, and United Network of Organ Sharing.

METHODS

The development of this Health Policy Statement was initiated by the Health Policy Committee at the American Thoracic Society. A further description of the idea development, framework development, and synthesis of the manuscript is described in the online supplement.

RESULTS

Underlying Ethical Principles

Three ethical principles frame our consideration of the DCDD health policy:

1. Acts that promote the opportunity to donate viable organs respect the patient's potential interest in becoming an organ donor. In controlled DCDD, actions must be taken on living persons that are not primarily intended to promote their survival but rather are intended to benefit potential recipients awaiting organ transplantation. Such acts may be justified through their promotion of the donor's legitimate interests in what becomes of their bodies after death (7).

2. The legitimacy of surrogate decision making for critically ill patients whose wishes are unknown extends to decisions regarding organ donation. Because critically ill patients frequently lack decisional capacity, surrogates have well-established roles in guiding decisions such as when to transition from curative to palliative care and when to withdraw or limit life-sustaining therapies. There are no compelling reasons that the legitimacy of a next-of-kin's or legally appointed surrogate's decision making should not also apply to choices regarding organ donation. Although this principle permits decisions to be made by a surrogate decision maker, it does not imply that the surrogate's preferences ought to supersede a patient's previously expressed preferences.

3. If real or perceived conflicts arise between the goals of providing optimal end-of-life care and the goals of procuring organs, delivery of quality end-of-life care should take priority. Organ procurement does not necessarily conflict with the provision of palliative care at the end of life. Because interventions intended to preserve organ function may respect the patient's donation preferences, even invasive interventions may be consistent with patient-centered end-of-life care. However, real or perceived conflicts may arise. Such incipient conflicts ought to

be resolved through maximal attention to the patients' expressed preferences for end-of-life care. Patients or their surrogates should be informed of how certain end-of-life treatment strategies may affect opportunities for donation before their initiation.

Consent Process

Throughout this document, we use the term "consent" to describe the active granting of approval to proceed with DCDD, whether this approval was granted by the patient *ante mortem* or by the patients' surrogate perimortem. This term was used nearly universally when development of this statement began. Since that time, the Association for Organ Procurement Organizations has advocated use of the term "authorization" to describe this process. The rationale for using "authorization" is based in its accordance with gift law, which applies to many aspects of organ donation. There also may be ethical reasons to consider changing to authorization. However, the committee agreed that to make this change in terminology, further ethical analysis was necessary. Further assessment may be particularly important in the context of DCDD, where all decisions and some procedures occur *ante mortem*, and decisions to donate may affect the timing and location of the withdrawal of life support.

First-person versus surrogate consent. Consent for organ donation is necessary before DCDD, in part because the DCDD process may entail the alteration of a patient's care plans to benefit others through organ donation (8, 9). Because organ procurement efforts may promote patients' legitimate interests in becoming organ donors, patients' previously expressed preferences for organ donation should be prioritized when they are known. Such "first-person consent" can take several forms: patients may register their desires to donate through the Department of Motor Vehicles donor registry, through an online donor registry, or by a durable power of attorney, or by explicitly stating their preferences in a living will or advanced directive.

Does the presence of first-person consent obviate the need to obtain consent for donation from surrogates? Legally, first-person consent is strongly championed in the Uniform Anatomical Gift Act, which grants the right for adults to make a donation decision before death and for donated organs to be recovered on that basis (10, 11). Under these laws, surrogates are not permitted to override a patient's decision to donate (11, 12). Furthermore, because these laws do not make a distinction based on how death is declared, first-person consent has been interpreted as providing legal authorization for organ donation whether that occurs after a determination of death based on neurological or circulatory criteria.

The legal authority of first-person consent should not diminish intensive care unit (ICU) clinicians' and OPOs' sensitivity to the impact of organ donation on surrogates. Intensivists may have to manage conflicts regarding views on donation between the patients and their surrogates. For the majority of DCDD cases in which the patient cannot communicate preferences, families have an integral role because their consent for the withdrawal of life-sustaining therapy is required even if organ donation has been authorized through first-person consent. Further research is needed to better understand the effects of organ donation on family members' bereavement and perceptions of the quality of end-of-life care after decisions to participate or not in the DCDD process.

ICU staff and OPO representatives should promote the patient's wishes by informing families when patients have previously expressed consent to donation. For patients who are potentially suitable candidates for DCDD, donation should be presented to the surrogate after a decision to withdraw life-sustaining

treatments. If patients have provided first-person consent for organ donation, those obtaining consent from surrogates for *ante mortem* procedures or withdrawal of support should consider using language that frames the conversation around a default assumption of donation. In circumstances of persisting disagreement, intensivists should seek to facilitate discussions between OPO representatives and surrogates. Ultimately, DCDD donation may not be possible if families are unwilling to consent to required *ante mortem* interventions or withdraw care at a time and location that does not support organ donation.

When should discussions regarding DCDD occur? There are several junctures during the course of critical illness leading to circulatory arrest when clinicians might notify the OPO and/or initiate discussions of donation with surrogates. As established previously (9, 13), the governing principle is that discussions with the patient and/or their surrogates regarding the withdrawal or limitation of life-sustaining therapy should occur before discussions of donation. A recent study indicated that such separation is required in the DCDD policies of 89% of pediatric hospitals (14); those lacking such a formal requirement should consider its adoption.

However, in all cases for which donation may be medically possible, patients or surrogates should be afforded the opportunity to discuss the full range of risks and benefits of withdrawing or limiting therapies, including the effects of these decisions on opportunities to donate. Thus, ICU clinicians should strive for timely notification of OPO representatives, defined as notification within 1 hour of identifying an impending death or decision to withdraw or limit life-sustaining therapy. This process may increase the time available to evaluate a patient's medical suitability for donation and to relay information about the opportunity to donate to families. In addition, timely notification may both improve the quality of consent and increase the proportion of eligible donors (15). As each case is unique, hospital clinicians and OPOs should collaboratively develop a family communication plan on a case-by-case basis to assess the best time to engage surrogates in donation discussions.

Who should obtain surrogate consent? The Centers for Medicare and Medicaid Services requires that the person obtaining consent for organ donation be either an OPO representative or a "designated requestor"—a hospital employee who has completed an OPO-approved training program (16). Some hospitals, typically those with level I trauma centers, have dedicated OPO staff on site who seek consent for donation (17). Similar to donation after neurologic determination of death, there are strong reasons to support the underlying concept that persons involved in DCDD discussions should be capable of disclosing information accurately, interacting compassionately with grieving families, and answering all relevant questions.

Skill, compassion, knowledge of donation processes, and having dedicated time are keys for an optimal process and successful outcome. Regardless of who coordinates consent discussions, potentials for conflict exist. When members of the ICU team lead consent discussions, there is potential for real or perceived conflicts between loyalty to the dying patient and duties to promote the social goal of increasing the supply of life-saving organ transplants (18). Similarly, OPO employees have interests in and responsibilities for increasing organ donation and transplantation. Therefore, individuals who seek consent for organ donation should always clearly disclose their organizational affiliation as well as their role in the donation process (19). Because it may be impossible to remove such potential conflicts entirely, optimal requestors will be those persons who are able to be transparent and are best able to relay information to families in a comprehensive, compassionate, and even-handed manner.

Interventions

Many invasive and noninvasive *ante mortem* interventions are commonly performed within the context of DCDD protocols. These often include the *ante mortem* administration of medications such as heparin to prevent the formation of emboli, vasodilators to improve organ perfusion, bronchoscopy to rule out infection, placement of a nasogastric tube to decompress the stomach, or the placement of arterial and/or venous cannulae for rapid access at the time of death. Before death, the patient may be prepped and draped for surgery and/or be moved to a new location, such as the operating room, for the withdrawal of life-sustaining treatments, dependent on individual hospital policies. Compassionate end-of-life care is still provided along with any treatment or medications the attending physician would routinely order without the DCD process in place. After the declaration of death, other interventions may be implemented, such as the administration of preservative solutions or use of extracorporeal membrane oxygenation (ECMO) to augment oxygen delivery (20–22).

Some physicians and ethicists have suggested that interventions such as ECMO are inappropriate because they are intended to benefit potential organ recipients rather than the patient (23–25). We agree that the best interests of the patient must be prioritized at all times. However, promoting the patient's wishes to donate organs may be consonant with the provision of high-quality end-of-life care (26, 27). The following framework is intended to preserve a focus on the priorities of the dying patient, including first person consent to donate organs.

Ante mortem interventions. *Ante mortem* interventions are ethically appropriate if they contribute to good transplant outcomes and have a low chance of harming the prospective donor. Furthermore, OPOs should ensure that use of such interventions is consistent with local laws and institutional policies. *Ante mortem* procedures and interventions that are performed solely to promote the donation of optimal organs include: (1) moving the patient to a different location to withdraw life support, (2) administering heparin and/or vasodilators, (3) cannulating large vessels, and (4) performing bronchoscopy.

To improve organ viability, the patient may be moved to the operating room (OR) before the withdrawal process to reduce the recovery time for organs after death occurs. This process could affect the quality of the dying process. However, we believe that quality of end-of-life care may be preserved if families are provided with an explanation and prepared in advance that the withdrawal process will take place in the OR. In addition, families should be offered similar support during the withdrawal process as they would experience in the ICU, such as allowing personal items to be brought into the OR, turning off unnecessary monitoring devices, and offering spiritual and palliative care support.

Heparin is often, but not always (28), administered before the cessation of circulation to prevent thrombosis. Although there is some concern that administration of heparin may pose a risk to some patients (25), the actual risks are likely to be exceedingly low given the short time to expected death (29, 30). Thus, with surrogate consent, the administration of *ante mortem* heparin is ethically permissible; the timing of its administration should comply with local laws and hospital policies.

Similarly, use of vasodilators is ethically acceptable given the same rationale. As with all *ante mortem* interventions, their use should be disclosed to families as care processes explicitly intended to facilitate organ donation.

As another example, if DCDD lung donation is under consideration, diagnostic bronchoscopy *pre* and perhaps *post mortem* after reintubation may usefully distinguish among organs of

varying viability. As the risks of a diagnostic bronchoscopy are minimal for the patients, this intervention is also ethically acceptable if clinicians believe it will contribute to good transplant outcomes and the rationale for bronchoscopy is disclosed to the surrogate.

Post mortem interventions. After the declaration of death, the use of several *post mortem* interventions has generated controversy because they may have the potential to reinitiate some physiologic functions. For example, most experts recommend that prospective lung donors be reintubated after declaration of death to promote organ viability (31–34). Such interventions are unlikely to result in reinitiation of circulation and/or peripheral oxygen delivery. In contrast, the use of ECMO after the declaration of death causes reinitiation of circulation and may stimulate brain or other organ functions. Use of ECMO in ways that clearly restore cerebral circulation is ethically and legally problematic (23). In some centers, ECMO is used for DCDD donors with occlusion of the thoracic aorta to reduce the chances of restoring cerebral circulation (21, 22). Despite this experience, the authors could not reach consensus on whether this use of ECMO is appropriate when using circulatory criteria for determining death. Therefore, ECMO in this setting requires further analysis to determine its clinical usefulness and ethical merit.

Declaration of Death

A central ethical and legal challenge in DCDD is to determine the timing of death for patients who die after the withdrawal of life-sustaining treatment. This is important because established ethical and legal standards subscribe to the “dead donor rule,” which states that removal of organs for transplantation must not precede the death of the organ donor. Defining the timing of death is also important because the duration of ischemia before organ recovery is closely related to the viability and quality of transplantable organs.

From a biological perspective, dying is a process that occurs over a continuum of time. But in the context of DCDD, the tension between the need for both “live organs” and a “dead donor” has required the development of very explicit criteria for declaring the “moment” of death, despite the absence of a biological basis for this degree of precision.

In the United States, death is defined as the irreversible cessation of either neurological or circulatory function (35). Several consensus documents state that permanent cessation of circulatory function may be declared when circulation has ceased for an interval between 2 and 5 minutes.

An important conceptual question is whether 2 minutes of circulatory cessation is sufficient to know that the loss of circulation is “irreversible,” as required by law. Some argue that because the patient could be resuscitated after a lack of circulation for 2 minutes, the loss of circulation is not irreversible (36–39). Others argue that this point is irrelevant, because the DCDD donor or surrogate has explicitly refused any attempts at resuscitation as part of the decision to withdraw life support and that spontaneous return of circulation is likely very rare after an interval of 60 to 75 seconds (20). In addition, a systematic review of the available literature showed that autoresuscitation, as defined by unassisted return of circulation, has not been reported to occur after withdrawal of life support in adults or children (20, 40, 41).

Importantly, although a philosophical debate exists regarding declaration of death in DCDD cases (42, 43), the committee supports DCDD as it is currently practiced. Specifically, if the patient or surrogate understands the circumstances of the determination of death, all members agreed that after 2 minutes of

absent circulation, physicians are legally authorized to declare death, and that organ recovery could proceed ethically. Although this agreement does not represent a philosophical or conceptual consensus regarding the precise timing of death, legal clarity is important from a public policy perspective. We therefore support standards whereby patients are legally dead after 2 minutes of absent mechanical circulation and respiratory function regardless of whether or not they are to become DCDD. In addition to this professional consensus that DCDD and the associated declaration of death as currently practiced are ethical, we believe that conflicting views on matters of morality need to be respected in morally pluralistic societies to the extent possible. Thus, for potentially eligible DCDD, we recommend that before withdrawal of life support, the surrogate be provided with a description of how and when patients will be declared dead. Surrogates also should be advised regarding the protocol for organ procurement. The provisions of this information and the voluntary nature of organ donation achieve the necessary respect for moral pluralism.

DCDD and the Provision of End-of-Life Care

There are several ways in which conflicts or perceived conflicts may arise in DCDD. Perceived conflicts may arise when persons with vested interests in obtaining consent for donation coordinate such discussions. Controlled DCDD also may present clinicians with a conflict between fulfilling the patients' wishes to receive quality end-of-life care while simultaneously becoming viable organ donors (44). Furthermore, some clinicians may refrain from participating in DCDD because of the perceived conflict between fidelity to the dying patient and stewarding scarce medical resources for the benefit of patients in need of transplant (45–47).

Despite the challenges for ICU clinicians to provide compassionate end-of-life care while furthering the interest of potential organ donors, conflicts generally can be managed by ensuring that evolving standards of quality end-of-life care are not sacrificed by the choice to become a DCDD donor (26, 48). In some ways, this task is easier in DCDD than in donation after neurologic determination of death. For patients who would like to be an organ donor but do not meet brain death criteria, DCDD offers an option to simultaneously accommodate both sets of wishes, because life support does not have to continue until brain death eventually occurs to donate. Thus, with the devoted attention of experienced clinical staff, DCDD might have the opportunity to enhance the quality of end-of-life care by respecting patients' wishes to donate without prolonging their death.

DCDD also may promote families' perceptions of the quality of the death by providing a tangible legacy for their loss. Many individuals believe strongly in organ donation, and many families find the act of donating organs to be meaningful during a time of loss (49, 50). However, because the decision to donate should not require a sacrifice in the quality or character of the end-of-life care provided (21), families should be given the opportunity to be present during the passing of their loved one, as they would be in the absence of donation. Furthermore, families must be prepared in advance for the emotional distress that could ensue if patients do not expire within a time interval compatible with donation. In such circumstances, accommodations must be readily available to continue compassionate end-of-life care outside the operating room.

The inextricable links between DCDD and end-of-life care suggest that hospitals need to have adequate physical and personnel resources available to perform DCDD. At a minimum,

those caring for potential DCDD donors should demonstrate core competencies in the provision of palliative care at the end of life (51). These core competencies include the ability to communicate openly and clearly with families, other ICU team members, and OPO staff; to withdraw unwanted life-sustaining therapies quickly and without precipitating distress; to manage symptoms of pain, anxiety, and breathlessness; and to provide emotional and spiritual support for bereaving families. These competencies could be met by professionals from many backgrounds, including attending physicians, fellows, physician extenders, and nurses from the disciplines of critical care or palliative care medicine. Regardless of training, however, these professionals must be empowered to make decisions to treat manifest distress, at least within the context of a protocol initiated by a supervising practitioner. If local institutional resources cannot support continuous supervision, DCDD should be undertaken during the time that supervision is available. In addition, representatives from the transplant team should have no role in the decision to withdraw care, the withdrawal process, or the declaration of death, and the OPO should have a limited and defined role in the withdrawal of support as it is related to location, timing, and monitoring.

Pediatric DCDD

Similar to experiences of adult clinicians, DCDD can be ethically challenging for pediatric clinicians (45, 47, 52). Issues related to the end-of-life process need to be addressed clearly and early in DCDD discussions with the family to ensure that parents can be with their children at the time of death (14, 53). Further discussion of special considerations of DCDD in pediatric donors is considered in the online supplement.

Future Research Directions

There are several outstanding issues related to the ethical and policy implications of DCDD. First, although first-person consent is legally sufficient for all forms of organ donation, it is uncertain what people intend when they express first-person consent to become a deceased organ donor. Further data should be obtained regarding whether people comprehend the distinction between declaring death on neurological or circulatory criteria and whether their preferences for donation are influenced by the distinct processes required by these two pathways to donation.

Second, it is important to better understand the impact of donation discussions and DCDD procedures on the quality of end-of-life care provided and on bereavement outcomes. Although it is difficult to directly examine the quality of death and dying for terminally ill patients (54), the experiences of surrogates of recently deceased patients may be used to gauge the quality of end-of-life care.

Third, more research is needed to understand factors that influence ICU clinicians' participation in DCDD and the barriers they perceive to performing DCDD well. Many clinicians perceive substantial deficiencies in their capacity to appropriately manage DCDD donors due to inadequate experience and education (44, 46, 47). It is important to identify ways to overcome these deficiencies in perceived self-efficacy.

Finally, further investigation of the appropriate dispersion of DCDD programs is needed. The Centers for Medicare and Medicaid Services and Joint Commission currently require all hospitals to establish and implement protocols for recovering DCDD organs (35, 55). Although all OPOs have expertise in DCDD and can assist in the donation process, DCDD requires a multidisciplinary approach. Because only hospitals with trauma centers and large numbers of ICU beds are likely to care for a substantial number

of potential DCDD donors (56), it is uncertain whether sufficient experience will accumulate at other institutions to enable adequate performance of this complex, multidisciplinary process. Addressing such questions at the policy level is essential given the current shortages of appropriately trained critical care personnel and the fact that these shortages will only worsen as critical care demand increases with an aging population.

CONCLUSIONS

In conclusion, this statement represents the collaborative framework of the American Thoracic Society, Society of Critical Care Medicine, International Society for Heart and Lung Transplantation, Association of Organ Procurement Organizations, and United Network of Organ Sharing regarding ethical and policy issues surrounding adult and pediatric DCDD. For those without existing first-person consent, we believe that consent of the surrogate for DCDD should be made after the decision to withdraw life support occurs. If first-person consent for donation exists, the discussion regarding the DCDD process should occur in a manner that offers the best collaborative plan to carry out the donation while supporting the family and donor's wishes. Consent should be obtained by individuals who are appropriately trained and should include specific discussion of the types of interventions that may be performed to promote successful organ transplantation as well as the process for declaring death. The committee supports the ability of physicians to declare death after 2 minutes of absent circulatory function, which we define as mechanical asystole. DCDD can occur successfully in children, and issues regarding consent (except that first-person consent is not applicable to the pediatric population), the use of *ante mortem* interventions, and the determination of death rest on similar principles as do those in adults. Finally, we recommend that hospitals participating in DCDD establish local DCDD protocols that incorporate guidelines for determining death and use of *ante mortem* interventions that are consistent with this framework and local or national laws.

This official statement was prepared by the American Thoracic Society Health Policy Committee

Members of the committee:

CYNTHIA J. GRIES, M.D., M.Sc.
 DOUGLAS B. WHITE, M.D., M.A.S.
 ROBERT D. TRUOG, M.D.
 JAMES DUBoIS, PH.D. D.Sc.
 CARMEN C. COSIO, M.D.
 SONNY DHANANI, M.D.
 KEVIN M. CHAN, M.D.
 PAUL CORRIS, M.D.
 JOHN DARK, M.D.
 GERALD FULDA, M.D.
 ALEXANDRA K. GLAZIER, J.D., M.P.H.
 ROBERT HIGGINS, M.D., M.S.H.A.
 ROBERT LOVE, M.D.
 DAVID P. MASON, M.D.
 THOMAS A. NAKAGAWA, M.D.
 RON SHAPIRO, M.D.
 SAM SHEMIE, M.D.
 MARY FRAN TRACY, PH.D., R.N.
 JOHN M. TRAVALINE, M.D.
 MARYAM VALAPOUR, M.D., PH.D.
 LORI WEST, M.D.
 DAVID ZAAS, M.D., M.B.A.
 SCOTT D. HALPERN, M.D., PH.D.

Author Disclosures: C.C.C. reported service as a member of the medical board or directors of LifeGift (Texas). S.D. reported service as chief medical officer/donation for the Trillium Gift of Life Network (Ontario). K.M.C. reported industry-sponsored grants from Alnylam Pharmaceuticals (\$100,001+), Broncus Technologies, Inc. (\$50,001–100,000), Gilead Sciences (\$100,001+), and XDX Expression Diagnostics, Inc. (\$100,001+). G.F. reported industry-sponsored grants from AstraZeneca (\$5,001–10,000), CSL Behring (\$10,001–50,000), and Pfizer (\$5,001–10,000). T.A.N. reported royalties from UpToDate, Inc. (up to \$1,000). R.S. reported service on advisory committees of Bristol-Myers Squibb (\$5,001–10,000) and StemCells, Inc. (\$5,001–10,000), receipt of lecture fees from Astellas (\$1,001–5,000) and Wyeth (\$1,001–5,000), and royalties from Informa Publications (\$1,001–5,000). S.S. reported service as medical advisor, organs and tissues, for Canadian Blood Services. M.F.T. reported royalties from Elsevier Publishing for the publication of book chapters (\$1,001–5,000) and service as the editor of the AACN Advanced Critical Care Journal (\$5,001–10,000). L.W. reported an industry-sponsored grant from Genzyme, Inc. (\$10,001–50,000). D.Z. reported consulting for APT Pharmaceuticals for outcomes monitoring (\$1,001–5,000) and Mpex Pharmaceuticals for data safety monitoring (\$1,001–5,000); he also served on advisory committees of CSL Behring (\$1,001–5,000), Ortho-McNeil (\$1,001–5,000), and Schering Plough (\$1,001–5,000), and received royalties from UpToDate, Inc. (up to \$1,000). C.J.G., D.B.W., R.D.T., J. DuBois, P.C., J. Dark, A.K.G., R.H., R.L., D.P.M., J.M.T., M.V., and S.D.H. reported that they had no relevant commercial interests.

References

- United Network for Organ Sharing. Donor designation (first-person consent) status by state. 2009 [accessed 2009 Jun 1]. Available from: <http://www.unos.org/inTheNews/factsheets.asp?fs=6>
- Morris NS, MacLean CD, Littenberg B. Literacy and health outcomes: a cross-sectional study in 1002 adults with diabetes. *BMC Fam Pract* 2006;7:49.
- Fang MC, Machtinger EL, Wang F, Schillinger D. Health literacy and anticoagulation-related outcomes among patients taking warfarin. *J Gen Intern Med* 2006;21:841–846.
- Mancuso CA, Rincon M. Impact of health literacy on longitudinal asthma outcomes. *J Gen Intern Med* 2006;21:813–817.
- Halpern SD, Barnes B, Hasz RD, Abt PL. Estimated supply of organ donors after circulatory determination of death: a population-based cohort study. *JAMA* 2010;304:2592–2594.
- Roy-Byrne PP, Craske MG, Stein MB, Sullivan G, Bystritsky A, Katon W, Golinelli D, Sherbourne CD. A randomized effectiveness trial of cognitive-behavioral therapy and medication for primary care panic disorder. *Arch Gen Psychiatry* 2005;62:290–298.
- Fost N. Reconsidering the dead donor rule: is it important that organ donors be dead? *Kennedy Inst Ethics J* 2004;14:249–260.
- Institute of Medicine. Non-heart-beating organ transplantation: practice and protocols. Washington, DC: National Academy Press; 2000.
- Bernat JL, D'Alessandro AM, Port FK, Bleck TP, Heard SO, Medina J, Rosenbaum SH, DeVita MA, Gaston RS, Merion RM, et al. Report of a national conference on donation after cardiac death. *Am J Transplant* 2006;6:281–291.
- Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. *JAMA* 1999;282:1737–1744.
- National Conference of Commissioners of Uniform State Laws. Uniform Anatomical Gift Act. 2009 [accessed 2013 Jun 14]. Available from: http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf
- American Psychiatric Association. Diagnostic and statistical manual of mental disorders (DSM-IV). Washington DC: American Psychiatric Press; 1994.
- DuBois JM, DeVita M. Donation after cardiac death in the United States: how to move forward. *Crit Care Med* 2006;34:3045–3047.
- Antommaria AHM, Trotchaud K, Kinlaw K, Hopkins PN, Frader J. Policies on donation after cardiac death at children's hospitals: a mixed-methods analysis of variation. *JAMA* 2009;301:1902–1908.
- Dickerson J, Valadka AB, Levert T, Davis K, Kurian M, Robertson CS. Organ donation rates in a neurosurgical intensive care unit. *J Neurosurg* 2002;97:811–814.
- Centers for Medicare and Medicaid Services. The CMS' interpretive guidelines for the hospital conditions of participation. Marblehead, MA: HC Pro Inc; 2004.
- Shafer TJ, Davis KD, Holtzman SM, Van Buren CT, Crafts NJ, Durand R. Location of in-house organ procurement organization staff in level

- I trauma centers increases conversion of potential donors to actual donors. *Transplantation* 2003;75:1330–1335.
18. Halpern SD. Care of the organ donor after circulatory determination of death: conflict or confluence of interest? In: Ravitsky V, Feister A, Caplan A, editors. Penn Center Guide to Bioethics. Springer: New York; 2009.
 19. Truog RD. Consent for organ donation—balancing conflicting ethical obligations. *N Engl J Med* 2008;358:1209–1211.
 20. Bernat JL, Capron AM, Bleck TP, Blosser S, Bratton SL, Childress JF, DeVita MA, Fulda GJ, Gries CJ, Mathur M, et al. The circulatory-respiratory determination of death in organ donation. *Crit Care Med* 2010;38:963–970.
 21. Magliocca JF, Magee JC, Rowe SA, Gravel MT, Chenault RH II, Merion RM, Punch JD, Bartlett RH, Hemmila MR. Extracorporeal support for organ donation after cardiac death effectively expands the donor pool. *J Trauma* 2005;58:1095–1101, discussion 1101–1102.
 22. Gravel MT, Arenas JD, Chenault R II, Magee JC, Rudich S, Maraschio M, DeRoy M, Miller W, Punch JD. Kidney transplantation from organ donors following cardiopulmonary death using extracorporeal membrane oxygenation support. *Ann Transplant* 2004;9:57–58.
 23. Doig CJ. Is the Canadian health care system ready for donation after cardiac death? A note of caution. *CMAJ* 2006;175:905–906.
 24. Van Norman GA. Another matter of life and death: what every anesthesiologist should know about the ethical, legal, and policy implications of the non-heart-beating cadaver organ donor. *Anesthesiology* 2003;98:763–773.
 25. Verheijde JL, Rady MY, McGregor J. Recovery of transplantable organs after cardiac or circulatory death: the end justifying the means. *Crit Care Med* 2007;35:1439–1440, author reply 1440–1441.
 26. Truog RD, Campbell ML, Curtis JR, Haas CE, Luce JM, Rubenfeld GD, Rushton CH, Kaufman DC; American Academy of Critical Care Medicine. Recommendations for end-of-life care in the intensive care unit: a consensus statement by the American College [corrected] of Critical Care Medicine. *Crit Care Med* 2008;36:953–963.
 27. DeVita MA, Caplan AL. Caring for organs or for patients? Ethical concerns about the Uniform Anatomical Gift Act (2006). *Ann Intern Med* 2007;147:876–879.
 28. Gries CJ, Curtis JR, Wall RJ, Engelberg RA. Family member satisfaction with end-of-life decision making in the ICU. *Chest* 2008;133:704–712.
 29. DuBois JM, Delmonico FL, D'Alessandro AM. When organ donors are still patients: is premortem use of heparin ethically acceptable? *Am J Crit Care* 2007;16:396–400.
 30. Steinberg D. The antemortem use of heparin in non-heart-beating organ transplantation: a justification based on the paradigm of altruism. *J Clin Ethics* 2003;14:18–25.
 31. Van Raemdonck DE, Rega FR, Neyrinck AP, Jannis N, Verleden GM, Lerut TE. Non-heart-beating donors. *Semin Thorac Cardiovasc Surg* 2004;16:309–321.
 32. Greco R, Cordovilla G, Sanz E, Benito J, Criado A, Gonzalez M, De Miguel E. Warm ischemic time tolerance after ventilated non-heart-beating lung donation in piglets. *Eur J Cardiothorac Surg* 1998;14:319–325.
 33. Hennington MH, D'Armini AM, Lemasters JJ, Egan TM. Cadaver lungs for transplantation: effect of ventilation with alveolar gas. *Transplantation* 1996;61:1009–1014.
 34. Van Raemdonck DE, Jannis NC, De Leyn PR, Flameng WJ, Lerut TE. Warm ischemic tolerance in collapsed pulmonary grafts is limited to 1 hour. *Ann Surg* 1998;228:788–796.
 35. Dew MA, Kormos RL, Roth LH, Murali S, DiMartini A, Griffith BP. Early post-transplant medical compliance and mental health predict physical morbidity and mortality one to three years after heart transplantation. *J Heart Lung Transplant* 1999;18:549–562.
 36. Gazmararian J, Baker D, Parker R, Blazer DG. A multivariate analysis of factors associated with depression: evaluating the role of health literacy as a potential contributor. *Arch Intern Med* 2000;160:3307–3314.
 37. Henning JC, Ansems JP. Photoionization threshold of the deep donor in Si-doped AlxGa1-xAs. *Phys Rev B Condens Matter* 1988;38:5772–5775.
 38. Joyner-Grantham J, Mount DL, McCorkle OD, Simmons DR, Ferrario CM, Cline DM. Self-reported influences of hopelessness, health literacy, lifestyle action, and patient inertia on blood pressure control in a hypertensive emergency department population. *Am J Med Sci* 2009;338:368–372.
 39. Dobbels F, Vanhaecke J, Dupont L, Nevens F, Verleden G, Pirenne J, De Geest S. Pretransplant predictors of posttransplant adherence and clinical outcome: an evidence base for pretransplant psychosocial screening. *Transplantation* 2009;87:1497–1504.
 40. Hornby K, Hornby L, Shemie SD. A systematic review of resuscitation after cardiac arrest. *Crit Care Med* 2010;38:1246–1253.
 41. Sheth KN, Nutter T, Stein DM, Scalea TM, Bernat JL. Autoresuscitation after asystole in patients being considered for organ donation. *Crit Care Med* 2012;40:158–161.
 42. Robertson JA. Death: merely biological? *Hastings Cent Rep* 1999;29:4, author reply 5.
 43. Marquis D. Are DCD donors dead? *Hastings Cent Rep* 2010;40:24–31.
 44. Davis TC, Long SW, Jackson RH, Mayeaux EJ, George RB, Murphy PW, Crouch MA. Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Fam Med* 1993;25:391–395.
 45. Curley MAQ, Harrison CH, Craig N, Lillehei CW, Micheli A, Laussen PC. Pediatric staff perspectives on organ donation after cardiac death in children. *Pediatr Crit Care Med* 2007;8:212–219.
 46. D'Alessandro AM, Peltier JW, Phelps JE. An empirical examination of the antecedents of the acceptance of donation after cardiac death by health care professionals. *Am J Transplant* 2008;8:193–200.
 47. Mandell MS, Zamudio S, Seem D, McGaw LJ, Wood G, Liehr P, Ethier A, D'Alessandro AM. National evaluation of healthcare provider attitudes toward organ donation after cardiac death. *Crit Care Med* 2006;34:2952–2958.
 48. Clarke EB, Curtis JR, Luce JM, Levy M, Danis M, Nelson J, Solomon MZ; Robert Wood Johnson Foundation Critical Care End-Of-Life Peer Workgroup Members. Quality indicators for end-of-life care in the intensive care unit. *Crit Care Med* 2003;31:2255–2262.
 49. Burroughs TE, Hong BA, Kappel DF, Freedman BK. The stability of family decisions to consent or refuse organ donation: would you do it again? *Psychosom Med* 1998;60:156–162.
 50. Siminoff LA, Lawrence RH, Arnold RM. Comparison of black and white families' experiences and perceptions regarding organ donation requests. *Crit Care Med* 2003;31:146–151.
 51. Kelso CM, Lyckholm LJ, Coyne PJ, Smith TJ. Palliative care consultation in the process of organ donation after cardiac death. *J Palliat Med* 2007;10:118–126.
 52. Mathur M, Taylor S, Tiras K, Wilson M, Abd-Allah S. Pediatric critical care nurses' perceptions, knowledge, and attitudes regarding organ donation after cardiac death. *Pediatr Crit Care Med* 2008;9:261–269.
 53. Rodrigue JR, Cornell DL, Howard RJ. Pediatric organ donation: what factors most influence parents' donation decisions? *Pediatr Crit Care Med* 2008;9:180–185.
 54. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J. Validation of toolkit after-death bereaved family member interview. *J Pain Symptom Manage* 2001;22:752–758.
 55. Kroenke K, Spitzer RL, Williams JB, Monahan PO, Löwe B. Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. *Ann Intern Med* 2007;146:317–325.
 56. Wells KB, Sherbourne C, Schoenbaum M, Duan N, Meredith L, Unützer J, Miranda J, Carney MF, Rubenstein LV. Impact of disseminating quality improvement programs for depression in managed primary care: a randomized controlled trial. *JAMA* 2000;283:212–220.