

An Official American Thoracic Society, International Society Of Heart And Lung Transplantation, Society Of Critical Care Medicine, And United Network Of Organ Sharing Statement: Ethical and Policy Considerations In Organ Donation After Circulatory Determination of Death

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At a Glance Commentary: The goal of this manuscript was to propose ethical and health policy statement regarding topics in DCDD that were controversial or not well described in the literature. This manuscripts concentrates on: 1) the informed consent process in DCDD, 2) pre- and post- mortem interventions for DCDD, 3) the determination of death in DCDD, 4) provisions of end-of-life care in DCDD donors and 5) pediatric DCDD.

Abstract:

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 prior to death, DCDD raises unique ethical and policy issues. Therefore, a collaborative of American Thoracic Society (ATS), Society of Critical Care Medicine, International Society of Heart and Lung Transplantation and United Network of Organ Sharing was established.

Objectives: To develop an ethical and health policy statement on adult and pediatric DCDD with clear relevance to critical care and transplantation communities.

Methods: A collaborative workshop was held at the 2009 ATS International Meeting during which didactic and break-out discussion sections were conducted on: 1) informed consent process, 2) pre- and post-mortem interventions, 3) determination of death in DCDD, 4) provisions of end-of-life care in DCDD donors and 5) pediatric DCDD. Group leaders drafted sections based on recommendations of the entire collaborative. A draft was circulated to workshop participants and ATS Health Policy Committee. A final draft was submitted for peer review and then approved by the executive committees of the participating societies.

Main Results: Specific ethical and health policy recommendations are made addressing the: 1) informed consent process, 2) pre- and post- mortem interventions, 3) determination of death in DCDD, 4) provisions of end-of-life care in DCDD donors and 5) pediatric DCDD.

Conclusions: This statement provides direction regarding some of the complex ethical issues surrounding DCDD. These recommendations can be used to help frame local and national policy on DCDD.

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Key words: organ donor, transplant, cardiac death, clinical ethics

Abbreviations:

ATS: American Thoracic Society

DCDD: Donation after Circulatory Determination of Death

DNDD: Donation after Neurologic Determination of Death

ECMO: Extracorporeal Membrane Oxygenation

ISHLT: International Society of Heart and Lung Transplantation

OPO: Organ Procurement Organization

OR: Operating Room

SCCM: Society of Critical Care Medicine

UNOS: United Network of Organ Sharing

Overview

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

1. Informed Consent

- a. When patients themselves have consented to organ donation, ICU staff and organ procurement organization (OPO) representatives should promote the patient's wishes by relaying this information to surrogates.
- b. Because such first-person consent may not have distinguished between donation after neurologic determination of death (DNDD) and DCDD, informed consent for DCDD still should be sought from patients' surrogates.
- c. All hospitals that manage DCDD donors should maintain formal policies prohibiting clinical staff or OPO representatives from initiating discussions about DCDD until after a decision is made to discontinue life-sustaining therapy. Discussions about donation can be initiated by surrogates prior to the decision to withdraw life-sustaining measures.

- d. Consent for DCDD should be obtained by individuals with the necessary experience and training in organ donation consent; when these individuals are representatives of OPOs, they should clearly identify themselves as such.

2. Interventions

- a. Use of pre-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.
- b. Pre-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) should be regarded as investigational and controversial.

3. Determination of death

- a. Donors can be declared dead after the cessation of circulation and respiratory function for 2 minutes.
- b. The consent process should include information related to the determination of death

4. End-of-Life-Care

- a. Surrogates should be prepared during the informed consent process for 1) how and where life sustaining therapies will be withdrawn, 2) the restraints

on the time they can spend with their loved one post-mortem, and 3) the possibility that the patient may not be declared dead within the time interval necessary for donation.

- b. Hospitals that participate in DCDD should ensure that experienced personnel with core competencies in palliative care are available to participate in end-of-life care.
- 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. The ethical principles related to consent, intervention, declaration of death and end-of-life care in pediatric DCDD patients are similar to those for adults.
- b. Pediatric centers should dedicate specific resources to develop guidelines and policy to optimize accepted DCDD practice.

Introduction

With more than 21,000 deceased donor transplantations performed in the US each year, transplantation has emerged as an established intervention for patients with advanced organ disease. [1] In 2008, a total of 9,461 candidates were too sick to be transplanted or died while awaiting transplantation.[1, 2] Because the supply of “traditional” donors after neurological determination of death is insufficient to provide

organs for all patients who might benefit from transplantation,[3, 4], other sources of organ recovery are being actively explored. Among the options available for obtaining additional transplantable organs, the Institute of Medicine 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.[5]

Although the potential supply of DCDD donors would be insufficient to eliminate the organ shortage, it does offer the potential for more than 2,000 additional transplants annually.[6]

Controlled DCDD entails the recovery of organs following cessation of circulation among patients with severe neurological, neuromuscular, or pulmonary disease for whom decisions are made to forego further life prolonging treatments. Although organs from such donors account for increasing proportions of solid-organ transplantations in the United States and elsewhere[7], DCDD raises complex medical and ethical issues.[1] Many of the unique ethical features of DCDD stem from the facts that: (a) consent for donation is obtained prior to the declaration of death and (b) several aspects of donor management geared towards ensuring organ viability must occur simultaneously with the provision of end-of-life care to dying patients

The increasing gap between the number of donors and recipients also affects children. Thus, DCDD programs have also been developed and implemented in pediatric hospitals. The extent to which the processes for consent, end-of-life care, and declaration of death differ in pediatric versus adult DCDD also requires consideration.

Because potential conflicts may exist between the goals of expanding the organ supply and optimizing care for the dying, guidelines are needed to help establish

standardized DCDD protocols. Specifically, guidelines are needed to: 1) define the content, approach and timing of the informed consent process; 2) develop acceptable interventions and procedures near the time of death; and 3) establish a framework for the declaration of death on the basis of circulatory criteria. To meet these needs, the American Thoracic Society Health Policy Committee developed this statement about the ethical and health policy consideration in DCDD with representation from other critical care and transplant societies including: Society of Critical Care Medicine (SCCM), International Society of Heart and Lung Transplantation (ISHLT), and United Network of Organ Sharing (UNOS).

Methodology

The idea for guideline development was discussed during the HPC monthly teleconference and other teleconferences with DCDD experts. During these discussions, it was decided that broad representation of transplant donors and recipients was necessary. Therefore, we sought further critical care representation from SCCM and transplant representation from the ISHLT and UNOS. A broad spectrum of ATS membership was also represented by including members of the Behavioral Science Assembly, Clinical Problems Assembly, Critical Care Assembly, Nursing Assembly, and the Ethics and Conflict of Interest Committee. Finally, we invited experts in bioethics and abdominal organ transplantation who were not previously affiliated with these organizations but who had relevant expertise in this statement's content.

In addition, during these teleconferences we designed the agenda for the full day workshop at the 2009 ATS International meeting in San Diego. In order to have the

highest impact on the DCD literature, topics were selected that were not well represented in the literature or topics that did not have a general consensus in the literature. The following topics were selected and discussed in a didactic session to review the literature on the 1) consent process, 2) the ability to predict death, 3) the interventions that are important for good outcomes 4) the ethical considerations of pre and post- mortem interventions and 5) the debate surrounding the declaration of death.

In the afternoon, workshop participants were divided into three discussion sections led by Drs. Scott D. Halpern, James DuBois and Douglas B. White on the topics of 1) the informed consent process, 2) pre and post mortem interventions, and 3) the declaration of death, respectively. After the discussion sessions, all workshop participants reconvened to form consensus to be used for establishing policy recommendations.

During the following months, the leaders of the discussion sections were charged with summarizing the findings of workshop for each of their sections. In addition, as few pediatric members attended the face-to-face meeting, the writing team contacted pediatric intensivists and transplant physicians to address some of the special issues relating to children. A draft that combined these contributions was developed by Dr. Gries and circulated to workshop participants and the Health Policy committee. The drafts were circulated via several emails. The document then underwent the peer review process per the ATS documents committee and was subsequently reviewed by the ATS Executive Committee of the Board of Directors. In addition the draft was reviewed by the Executive Committee of all participating societies.

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 anonymous people 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.[8]

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 life-sustaining therapies. There are no compelling reasons why 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.

Informed Consent Process

First-person vs. surrogate consent

Consent is required for DCDD because the process entails the alteration of a patient's care plans to benefit others through organ donation.[9, 10] 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 provide an oral directive to their loved ones, may register their desires to donate on their driver's license, donor card, or through an online donor registry; document their preferences with their primary care provider or a durable power of attorney; or explicitly state 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 provides sufficient grounds for organ procurement in all 50 United States and Washington, D.C..[11] Some states have gone beyond this permissive standard to legally prohibit surrogates from overriding a patient's previously expressed consent to donation.[11] Respect for first-person consent is also instantiated strongly in the 2006 revision to the Uniform Anatomical Gift Act,[12] which had been adopted in 42 states and Washington, D.C. at the time of this writing.[12]

Despite the legal authority of first-person consent, ICU clinicians and OPOs are understandably sensitive to the impact of organ donation on surrogates. Intensivists may have to manage conflicts regarding views on donation between the patients and their surrogates. Thus, despite the legal standing of first-person consent, surrogate consent is still sought in the majority of cases of DNDD.[13, 14] Corresponding data are unavailable in DCDD. However, our experience is that familial agreement is sought in virtually all DCDD cases. Although first-person consent is of primary importance for both DCDD and DNDD, we support including family members in the decision making process. First, in the simple consent processes of first-person donor designations, patients' stated preferences might not apply equally to DNDD and DCDD and the distinction will rarely have been specified. If people believe they are providing guidance for what becomes of their bodies following death, it is unclear how such preferences apply to the pre-mortem decision-making required in DCDD. Second, although the effects of organ donation on bereavement and perceptions of the quality of end-of-life

care have yet to be elucidated, procuring organs against the surrogate's wishes could exacerbate surrogates' sense of loss and degrade public trust in organ transplantation. Indeed, in a survey of families with whom DNDD had recently been discussed, nearly half did not support a policy in which first-person consent would have been deemed sufficient to procure organs.[15]

Despite these concerns with the sufficiency of first-person consent, 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, this option should be presented to the surrogate following a decision to withdraw life-sustaining treatments. If patients have provided first-person consent for organ donation, those obtaining consent from surrogates may use language that frames the conversation around a default assumption of donation while still making clear that surrogates have the right to refuse.

When should surrogate consent be sought?

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, [16, 17] the governing principle is that discussions with families regarding organ donation should be separated from and subsequent to decisions to withdraw life-sustaining therapy. Therefore, the OPO representatives or members of the transplant team should not participate in any discussion regarding the decision to remove or retain artificial life support and

medication. A recent study indicated that such separation is required in the DCDD policies of 89% of pediatric hospitals;[18] those lacking such a formal requirement should consider its adoption.

However, decisions to donate may often entail deliberative processes rather than snap judgments. Thus, if families independently choose to discuss the possibility of organ donation prior to final decisions to withdraw life-sustaining therapy, clinicians should support this choice through provision of relevant donation information, including inviting OPO representatives to the bedside for educational purposes. In the more common circumstances when families do not initiate donation discussions, timely notification of OPO representatives – defined as notification within one hour of identifying an impending death or decision to withdraw life-sustaining therapy – increases the time available to evaluate a patient’s medical suitability for donation and to relay information about the opportunity to donate to families in less pressured settings. Thus, timely notification may both improve the quality of informed consent and increase the proportion of eligible donors.[19] However, OPO notification should not be so rapid as to hurry discussions between the surrogate and ICU clinicians regarding the withdrawal of life-sustaining therapies.

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.[20]

Some hospitals, typically those with level I trauma centers, employ in-house transplant coordinators who seek consent for donation.[21] Similar to DNDD, 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, and neutrality better characterize an appropriate requestor than does employment or professional background. Regardless of who coordinates informed consent discussions, potentials for conflict exist. When members of the ICU team lead informed 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.[22] Alternatively, OPO employees or hospital-employed transplant coordinators could be mistaken for part of the treating medical team and therefore should clearly identify themselves as an OPO representative.[23] For example, representing oneself as a “member of the clinical team” or as “a counselor who works with grieving families” is difficult to justify when the requestor would never have met the surrogate were it not for the potential of organ donation. Because it may be impossible to remove such potential conflicts entirely, optimal requestors will be those persons who are best able to relay information to families in a comprehensive, compassionate, and even-handed manner.

Interventions

Many invasive and non-invasive pre-mortem interventions are commonly performed within the context of DCDD protocols. These often include the pre-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 naso-gastric tube to decompress the stomach; or the placement of arterial and/or venous cannulae for rapid access at the time of death. Prior to 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. Following the declaration of death, other interventions may be implemented such as the administration of preservative solutions or use of extracorporeal membrane oxygenation to augment oxygen delivery.[24-26]

Some physicians and ethicists have suggested that interventions such as extracorporeal membrane oxygenation are inappropriate because they are intended to benefit potential organ recipients rather than the patient.[27-29] 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.[30, 31] The following guidelines are intended to preserve a focus on the priorities of the dying patient, including wishes to donate organs.

Pre-mortem Interventions

Pre-mortem interventions are ethically appropriate if they contribute to good transplantation 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. Pre-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.

In order to improve organ viability, the patient may be moved to the operating room (OR) prior to 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[32], administered prior to the cessation of circulation in order to prevent thrombosis. While there is some concern that administration of heparin may pose a risk to some patients,[29] the actual risks are likely to be exceedingly low given the short time to expected death. [33, 34] Thus, with consent, the administration of heparin is ethically permissible; the timing of its administration should comply with local laws and hospital policies.

Similarly, vasodilators are ethically acceptable given the same rationale. As with all pre-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 following re-intubation 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 as part of the consent for donation.

Post-mortem Interventions

Following the declaration of death, the use of several post-mortem interventions has generated controversy because they may have the potential to re-initiate some physiologic functions. For example, most experts recommend that prospective lung donors be re-intubated after declaration of death in order to promote organ viability.[35-38] Such interventions are unlikely to result in re-initiation of circulation and/or peripheral oxygen delivery. In contrast, the use of extracorporeal membrane oxygenation (ECMO) following the declaration of death causes re-initiation of circulation and may stimulate brain or other organ functions. Use of ECMO in ways that clearly restore cerebral circulation is ethically problematic [24]. In some centers, ECMO is used for DCDD donors with occlusion of the thoracic aorta to reduce the chances of restoring cerebral circulation.[25, 26] However, 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 should be regarded as investigational and controversial, and in need of further analysis to determine its clinical utility 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 standards subscribe to the “dead donor rule” which states that removal of organs for transplantation must not precede the death of the organ donor. In this regard, defining the timing of death is important because the duration of ischemia prior to 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.[39] 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.[9, 40-42]

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.[43-46] Others argue that this point is irrelevant since the DCDD donor or surrogate has refused any attempts at resuscitation, and that spontaneous return of circulation is likely very rare after an interval of 60-75 seconds.[24] 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. [47]

Conceptually, this controversy revolves around whether DCDD donors are actually dead, or whether they are in the process of dying. Practically, this distinction may be of little relevance because without circulation (and in the absence of attempts at resuscitation) the patient is irreversibly dying after 2 minutes. Furthermore, ethically, the focus on the precise timing of death seems inappropriately detached from the patient's perspective. Hence, it has been argued that if a dying patient truly recognizes their condition and wishes to donate organs, then we ought not deny such autonomous expressions of will merely because clinicians have not precisely define the moment of death.[48]

Importantly, although controversy exists as to whether DCDD conforms to the dead donor rule, [49, 50] the committee supports DCDD as it is currently practiced. Specifically, with appropriate consent by the patient or surrogate to donation under

these circumstances, all members agreed that after 2 minutes of absent circulation, physicians are 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 may be more important from a public policy perspective. We therefore believe DCDD donors should be considered to be legally dead after 2 minutes of absent mechanical circulation and respiratory function.

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. It therefore is necessary to ensure that individuals are free to refrain from acting against their deeply held moral beliefs. The voluntary nature of organ donation accomplishes this, provided that consent is truly informed, including the provision of information regarding the circumstances under which death is declared in DCDD.

In addition to describing the procedures that we will perform, we recommend that consent language include an explicit description of the point at which a patient in the process of dying will be declared dead. The consent process should explain in detail the point at which organs will be procured to give families the opportunity to determine whether this is consistent with the patient's value and preferences.

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 informed consent 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.[51] 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.[52-54] Is it possible for ICU clinicians to simultaneously provide compassionate end-of-life care – serving as guardians of a dignified death for the 20% of Americans who die in ICUs[55] – while also furthering the interests of potential organ donors and recipients?

Despite the challenges of maintaining these dual roles, 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. [56, 57] In some ways, this task is easier in DCDD than in DNDD. For patients that do not meet brain death criteria but have the desire to forgo life-sustaining therapies and become an organ donor,[58] DCDD offers an option to simultaneously accommodate both sets of wishes because life support does not have to continue until brain death eventually occurs in order to donate. Thus, with the devoted attention of experienced clinical staff, DCDD might enhance the quality of end-of-life care by promoting 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.[59, 60] However, because the decision to donate should not require a sacrifice in the quality or character of the end-of-life care provided, [22] 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 personal 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. These core competencies include the ability to communicate openly and clearly with families, other ICU team members, and OPO representatives; 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. Where local institutional resources do not allow for such supervision, DCDD should not be undertaken. In addition, representatives from the transplant team or OPO should have no role in the decision to withdraw care, the withdrawal process, or the declaration of death.

Pediatric DCDD

Recovery, allocation, and transplantation of organs from infants and small children can pose challenges due to constraints imposed by their size and weight. Nonetheless, all infants and children should be considered for potential DCDD when death is imminent. Mortality on the pediatric waiting list is highest among children less than a year of age,[61] and there is potential to increase transplants and reduce deaths in this and all age groups with DCDD. The American Academy of Pediatrics supports DCDD as a reasonable way to recover more organs for transplantation.[62]

Single-center studies in several children's' hospitals have shown potential for DCDD donors to increase the number of organs for pediatric transplantation.[63-65] As such, the numbers of pediatric DCDD have increased during the past 10 years.[2, 66, 67] Although a small percentage of dying children will be eligible DCDD donors at any given pediatric center, the overall national impact can potentially provide a significant increase in the number of organs available for transplantation. Success with transplanting DCDD

kidneys and livers into children have been reported at many centers, [68] recently, 3 hearts were transplanted from infant DCDD donors under an experimental protocol.[69]

The desire of the family to allow their child to become a donor has been a driving force for DCDD in pediatrics.[70] The decision to donate in all cases, after DNDD or DCDD, involving children is left to the surrogate decision maker. First person consent is rarely a consideration in children. Appropriate consent for pre- and post-mortem interventions is equally relevant in children as in adults. Similarly, from an ethical perspective, the declaration of death after the withdrawal of life sustaining treatment can proceed in children as in adult DCDD donors.

Similar to experiences of adult clinicians, DCDD can be ethically challenging for pediatric clinicians.[66, 70, 71] The use of dedicated personnel to educate and support staff regarding DCDD may alleviate these concerns and allow for improved rates of DCDD organ recovery. Pediatric centers should dedicate specific resources to develop guidelines and policy to optimize accepted DCDD practice. Encouraging program development to meet the needs of families during end-of-life care has resulted in successful implementation of DCDD donation in pediatric centers.[72] 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.[73, 74]

Future research directions

There are several outstanding questions related to the ethical and policy implications of DCDD. Many of these questions are empirically testable, and each represents an important direction for future study. First, it is uncertain what people understand and intend when they express first-person consent to become a deceased organ donor. Evidence 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, could provide guidance for the degree to which first-person consent ought to be prioritized in DCDD.

Second, it is our impression that tools to predict death following the withdrawal of life-sustaining therapy[75, 76] are infrequently used to guide DCDD. In an effort to improve the evidence surrounding this important issue, future research should (1) explore why these tools are or are not used presently, (2) compare new and existing tools with clinicians' predictions of whether death will occur in a reasonable time frame, and (3) determine whether increased utilization might improve the quality of informed consent for DCDD or bereavement outcomes. An enhanced capacity to predict death within a prescribed time interval might reduce the resources expended on failed DCDD attempts and limit the frequency with which families must bear the emotional burden of being told that their loved one was ineligible to donate after hopes had been raised.

Third, 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,[77] the experiences of surrogates of recently deceased patients may be used to gauge the quality of end-of-life care.[78-81]

Fourth, 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 education.[53, 82] [51] It is important to identify ways to overcome these deficiencies in perceived self-efficacy.

Fifth, a detailed exploration of the ethical and health policy issues related to uncontrolled DCDD is necessary.

Finally, we might ask what the appropriate diffusion of DCDD programs might look like. The Centers for Medicare and Medicaid Services and Joint Commission currently require all hospitals to establish and implement protocols for recovering DCDD organs.[39, 83] However, because only hospitals with trauma centers and large numbers of ICU beds are likely to care for a substantial number of potential DCDD donors,[6] 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 recommendations of ATS, SCCM, ISHLT, and UNOS regarding ethical and policy issues surrounding adult and pediatric DCDD. We believe that an informed consent process for DCDD should be made after the decision to withdraw life support occurs. Consent should be obtained by individuals who are appropriately trained, and should include specific discussion of the types of interventions that may be performed in order to promote successful organ transplantation, as well as descriptions of the manner and circumstances in which death will be declared. 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, the use of pre-mortem interventions, and the determination of death rest on similar principles as do those in adults. Finally, we recommend that hospitals that participate in DCDD establish local DCDD protocols that incorporate guidelines for determining death and using pre-mortem interventions that are consistent with these guidelines and local or national laws.

1. United Network for Organ Sharing. *Donor designation (first-person consent) status by state*. 2009 [cited 2009 June 1]; Available from: <http://www.unos.org/inTheNews/factsheets.asp?fs=6>.
2. *2004 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 1994-2003*. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation, Rockville, MD; United Network for Organ Sharing, Richmond, VA; University Renal Research and Education Association, Ann Arbor, MI. .
3. Guadagnoli E, Christiansen CL, Beasley CL. Potential organ-donor supply and efficiency of organ procurement organizations. *Health Care Financing Review* 2003;24(4):101-10.
4. Sheehy E, Conrad SL, Brigham LE, et al. Estimating the number of potential organ donors in the United States. *New England Journal of Medicine* 2003;349(7):667-74.
5. Institute of Medicine Committee on Increasing Rates of Organ Donation. *Organ Donation: Opportunities for Action*. Washington, D.C.: National Academy Press; 2006.
6. Halpern SD, Abt PL. Incidence and distribution of potential donors after circulatory determination of death in U.S. ICUs. *Am J Respir Crit Care Med* 181;2010:A6861
7. Organ Procurement and Transplantation Network. *Current Data*. Accessed February 2, 2010 at: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>. 2010.

8. Fost, N., *Reconsidering the dead donor rule: is it important that organ donors be dead?* Kennedy Inst Ethics J, 2004. **14**(3): p. 249-60.
9. Institute of Medicine, *Non-heart-beating organ transplantation. Practice and protocols.* 2000, Washington, DC: National Academy Press.
10. Bernat, J.L., et al., *Report of a national conference on donation after cardiac death.* American Journal of Transplantation, 2006. **6**(2): p. 281-291.
11. *Donor designation (first-person consent) status by state. 2009. (Accessed June 1, 2009, at <http://www.unos.org/inTheNews/factsheets.asp?fs=6>).*
12. National Conference of Commissioners of Uniform State Laws. *Uniform Anatomical Gift Act.* 2009 [cited 2009 June 1]; Available from: <http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=2&tabid=72>.
13. Healy, K., *Altruism as an organizational problem: The case of organ procurement.* American Sociological Review, 2004. **69**(3): p. 387-404.
14. Wendler, D. and N. Dickert, *The consent process for cadaveric organ procurement - How does it work? How can it be improved?* Jama-Journal of the American Medical Association, 2001. **285**(3): p. 329-333.
15. Rodrigue, J.R., D.L. Cornell, and R.J. Howard, *Attitudes toward financial incentives, donor authorization, and presumed consent among next-of-kin who consented vs. refused organ donation.* Transplantation, 2006. **81**(9): p. 1249-1256.
16. Bernat, J.L., et al., *Report of a national conference on donation after cardiac death.* American Journal of Transplantation, 2006. **6**(2): p. 281-91.

17. DuBois, J.M. and M. DeVita, *Donation after cardiac death in the United States: how to move forward*. Critical Care Medicine, 2006. **34**(12): p. 3045-7.
18. Antommaria, A.H.M., et al., *Policies on donation after cardiac death at Children's Hospitals: A mixed-methods analysis of variation*. JAMA, 2009. **301**(18): p. 1902-1908.
19. Dickerson, J., et al., *Organ donation rates in a neurosurgical intensive care unit*. Journal of Neurosurgery, 2002. **97**: p. 811-4.
20. Centers for Medicare and Medicaid Services, *The CMS' Interpretive Guidelines for the Hospital Conditions of Participation*. 2004, Marblehead, MA: HC Pro Inc.
21. Shafer, T.J., et al., *Location of in-house organ procurement organization staff in level I trauma centers increases conversion of potential donors to actual donors*. Transplantation, 2003. **75**: p. 1330-35.
22. Halpern, S.D., *Care of the organ donor after circulatory determination of death: Conflict or confluence of interest?*, in *Penn Center Guide to Bioethics*, V. Ravitsky, A. Feister, and A. Caplan, Editors. 2009, Springer: New York.
23. Truog, R.D., *Consent for organ donation -- balancing conflicting ethical obligations*. N Engl J Med, 2008. **358**: p. 1209-11.
24. Bernat, J.L., et al., *The circulatory-respiratory determination of death in organ donation*. Crit Care Med. **38**(3): p. 963-70.
25. Magliocca, J.F., et al., *Extracorporeal support for organ donation after cardiac death effectively expands the donor pool*. J Trauma, 2005. **58**(6): p. 1095-101; discussion 1101-2.

26. Gravel, M.T., et al., *Kidney transplantation from organ donors following cardiopulmonary death using extracorporeal membrane oxygenation support*. *Ann Transplant*, 2004. **9**(1): p. 57-8.
27. Doig, C.J., *Is the Canadian health care system ready for donation after cardiac death? A note of caution*. *Canadian Medical Association Journal*, 2006. **175**(8): p. 905-6.
28. Van Norman, G.A., *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**(3): p. 763-773.
29. Verheijde, J., M. Rady, and J. McGregor, *Recovery of transplantable organs after cardiac or circulatory death: The end justifying the means*. *Critical Care Medicine*, 2007. **35**(5): p. 1439-1440.
30. Truog, R.D., et al., *Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American Academy of Critical Care Medicine*. *Critical Care Medicine*, 2008. **36**(3): p. 953-963.
31. DeVita, M.A. and A.L. Caplan, *Caring for organs or for patients? Ethical concerns about the Uniform Anatomical Gift Act (2006)*. *Annals of Internal Medicine*, 2007. **147**(12): p. 876-879.
32. Erasmus ME, Verschuuren EAM, Nijkamp DM, Vermeyden JW, van der Bij W. *Lung Transplantation from Nonheparinized Category III Non-Heart-Beating Donors. A Single-Centre Report*. *Transplantation*;89(4):452-7.

33. DuBois, J.M., F.L. Delmonico, and A.M. D'Alessandro, *When organ donors are still patients: Is pre-mortem use of heparin ethically acceptable?* American Journal of Critical Care, 2007. **16**(4): p. 396-400.
34. 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**(1-2): p. 18-25.
35. Van Raemdonck, D.E., et al., *Non-heart-beating donors.* Semin Thorac Cardiovasc Surg, 2004. **16**(4): p. 309-21.
36. Greco, R., et al., *Warm ischemic time tolerance after ventilated non-heart-beating lung donation in piglets.* Eur J Cardiothorac Surg, 1998. **14**(3): p. 319-25.
37. Hennington, M.H., et al., *Cadaver lungs for transplantation. Effect of ventilation with alveolar gas.* Transplantation, 1996. **61**(7): p. 1009-14.
38. Van Raemdonck, D.E., et al., *Warm ischemic tolerance in collapsed pulmonary grafts is limited to 1 hour.* Ann Surg, 1998. **228**(6): p. 788-96.
39. *The Joint Commission. Healthcare at the crossroads: Strategies for narrowing organ donation gap and protecting patients.* Accessed January 27, 2010 at: http://www.jointcommission.org/NR/rdonlyres/E4E7DD3F-3FDF-4ACC-B69E-AEF3A1743AB0/0/organ_donation_white_paper.pdf; 2004.
40. Bernat, J.L., et al., *The circulatory-respiratory determination of death in organ donation.* Crit Care Med, 2010. **38**(3): p. 963-70.
41. Bernat JL, D'Alessandro AM, Port FK, et al. *Report of a national conference on donation after cardiac death.* Am J Transplantation 2006: 6:281-291.

42. *Ethics Committee, American College of Critical Care Medicine and Society of Critical Care Medicine: Recommendations for non-heartbeating organ donation. A position paper by the Ethics Committee. Crit Care Med 2001; 29:1826-1831.*
43. *Truog RD, Cochrane TI: The truth about "donation after cardiac death." J Clin Ethics 2006; 17:133-136.*
44. *Truog RD, Robinson WM: Role of brain death and the dead-donor rule in the ethics of organ transplantation. Crit Care Med 2003; 31:2391-2396.*
45. *Truog RD, Miller FG: The dead donor rule and organ transplantation. N Engl J Med 2008; 359:674-675.*
46. *Miller FG, Truog RD: Rethinking the ethics of vital organ donations. Hastings Cent Rep 2008; 38(6):38-46.*
47. *Hornby, K., L. Hornby, and S.D. Shemie, A systematic review of autoresuscitation after cardiac arrest. Crit Care Med, 2010. 38(5): p. 1246-53.*
48. *Halpern, S.D. and R.D. Truog, Organ donors after circulatory determination of death: not necessarily dead, and it does not necessarily matter. Crit Care Med, 2010. 38(3): p. 1011-2.*
49. *Robertson, J.A., Death: merely biological? Hastings Cent Rep, 1999. 29(1): p. 4; author reply 5.*
50. *Marquis, D., Are DCD donors dead? Hastings Cent Rep, 2010. 40(3): p. 24-31.*
51. *Hart JL, Kohn R, Wallace M, Halpern SD. Perceptions of donation after circulatory determination of death among critical care physicians and nurses. Am J Respir Crit Care Med 181; 2010: A6690*

52. Curley, M.A.Q., et al., *Pediatric staff perspectives on organ donation after cardiac death in children*. *Pediatric Critical Care Medicine*, 2007. **8**: p. 212-9.
53. D'Alessandro, A.M., J.W. Peltier, and J.E. Phelps, *An empirical examination of the antecedents of the acceptance of donation after cardiac death by health care professionals*. *American Journal of Transplantation*, 2008. **7**: p. 1-8.
54. Mandell, M.S., et al., *National evaluation of healthcare provider attitudes toward organ donation after cardiac death*. *Critical Care Medicine*, 2006. **34**(12): p. 2952-2958.
55. Angus, D.C., et al., *Use of intensive care at the end of life in the United States: an epidemiologic study*. *Critical Care Medicine*, 2004. **32**(3): p. 638-43.
56. Truog, R.D., et al., *Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American Academy of Critical Care Medicine*. *Critical Care Medicine*, 2008. **36**(3): p. 953-963.
57. Clarke, E.B., et al., *Quality indicators for end-of-life care in the intensive care unit*. *Critical Care Medicine*, 2003. **31**(9): p. 2255-2262.
58. DeVita, M.A. and A.L. Caplan, *Caring for organs or for patients? Ethical concerns about the Uniform Anatomical Gift Act (2006)*. *Ann Intern Med*, 2007. **147**(12): p. 876-879.
59. Burroughs, T., et al., *The stability of family decisions to consent or refuse organ donation: Would you do it again?* *Psychosomatic Medicine*, 1998. **60**(2): p. 156-162.

60. Siminoff, L.A., R.H. Lawrence, and R.M. Arnold, *Comparison of black and white families' experiences and perceptions regarding organ donation requests*. Crit Care Med, 2003. **31**(1): p. 146-51.
61. Kolovos, N.S., P. Webster, and S.L. Bratton, *Donation after cardiac death in pediatric critical care*. Pediatr Crit Care Med, 2007. **8**(1): p. 47-9.
62. American Academy of Pediatrics "Policy Statement- pediatric organ donation and Transplantation. *Pediatrics* 2010; 125:822-828. .
63. Koogler, T. and A.T. Costarino, Jr., *The potential benefits of the pediatric nonheartbeating organ donor*. Pediatrics, 1998. **101**(6): p. 1049-52.
64. Durall, A.L., P.C. Laussen, and A.G. Randolph, *Potential for donation after cardiac death in a children's hospital*. Pediatrics, 2007. **119**(1): p. e219-24.
65. Pleacher, K.M., et al., *Impact of a pediatric donation after cardiac death program*. Pediatr Crit Care Med, 2009. **10**(2): p. 166-70.
66. Mathur, M., et al., *Pediatric critical care nurses' perceptions, knowledge, and attitudes regarding organ donation after cardiac death*. Pediatr Crit Care Med, 2008. **9**(3): p. 261-9.
67. Mazor, R. and H.P. Baden, *Trends in pediatric organ donation after cardiac death*. Pediatrics, 2007. **120**(4): p. e960-6.
68. de Vries, E.E., M.G. Snoeijs, and E. van Heurn, *Kidney donation from children after cardiac death*. Crit Care Med. **38**(1): p. 249-53.
69. Boucek, M.M., et al., *Pediatric heart transplantation after declaration of cardiocirculatory death*. N Engl J Med, 2008. **359**(7): p. 709-14.

70. Curley, M.A., et al., *Pediatric staff perspectives on organ donation after cardiac death in children*. *Pediatr Crit Care Med*, 2007. **8**(3): p. 212-9.
71. Mandell, M.S., et al., *National evaluation of healthcare provider attitudes toward organ donation after cardiac death*. *Crit Care Med*, 2006. **34**(12): p. 2952-8.
72. Naim, M.Y., et al., *The Children's Hospital of Philadelphia's experience with donation after cardiac death*. *Crit Care Med*, 2008. **36**(6): p. 1729-33.
73. Rodrigue, J.R., D.L. Cornell, and R.J. Howard, *Pediatric organ donation: what factors most influence parents' donation decisions?* *Pediatr Crit Care Med*, 2008. **9**(2): p. 180-5.
74. Antommaria, A.H., et al., *Policies on donation after cardiac death at children's hospitals: a mixed-methods analysis of variation*. *JAMA*, 2009. **301**(18): p. 1902-8.
75. DeVita, M.A., et al., *Donors after cardiac death: validation of identification criteria (DVIC) study for predictors of rapid death*. *American Journal of Transplantation*, 2008. **8**(2): p. 432-41.
76. Lewis, J., et al., *Development of the University of Wisconsin donation after cardiac death evaluation tool*. *Progress in Transplantation*, 2003. **13**(4): p. 265-73.
77. Teno, J.M., et al., *Validation of Toolkit After-Death Bereaved Family Member Interview*. *J Pain Symptom Manage*, 2001. **22**(3): p. 752-8.
78. Curtis, J.R., et al., *A measure of the quality of dying and death. Initial validation using after-death interviews with family members*. *J Pain Symptom Manage*, 2002. **24**(1): p. 17-31.

79. Lynn, J., et al., *Perceptions by family members of the dying experience of older and seriously ill patients. SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments.* Ann Intern Med, 1997. **126**(2): p. 97-106.
80. Teno, J.M., et al., *Family perspectives on end-of-life care at the last place of care.* JAMA, 2004. **291**(1): p. 88-93.
81. Casarett, D., et al., *A Nationwide VA Palliative Care Quality Measure: The Family Assessment of Treatment at the End of Life.* Journal of Palliative Medicine, 2008. **11**(1): p. 68-75.
82. Mandell, M.S., et al., *National evaluation of healthcare provider attitudes toward organ donation after cardiac death.* Critical Care Medicine, 2006. **34**(12): p. 2952-8.
83. *Centers for Medicare and Medicaid Services. The CMS' Interpretive Guidelines for the Hospital Conditions of Participation.* Marblehead, MA: HC Pro Inc; 2004.