



POLICY STATEMENT

Ethical Controversies in Organ Donation After Circulatory Death

COMMITTEE ON BIOETHICS

KEY WORDS

bioethics, children, circulatory death, ethics, organ donation, organ procurement

ABBREVIATIONS

DCD—donation after circulatory death

ECMO—extracorporeal membrane oxygenation

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www.pediatrics.org/cgi/doi/10.1542/peds.2013-0672

doi:10.1542/peds.2013-0672

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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abstract

FREE

The persistent mismatch between the supply of and need for transplantable organs has led to efforts to increase the supply, including controlled donation after circulatory death (DCD). Controlled DCD involves organ recovery after the planned withdrawal of life-sustaining treatment and the declaration of death according to the cardiorespiratory criteria. Two central ethical issues in DCD are when organ recovery can begin and how to manage conflicts of interests. The “dead donor rule” should be maintained, and donors in cases of DCD should only be declared dead after the permanent cessation of circulatory function. Permanence is generally established by a 2- to 5-minute waiting period. Given ongoing controversy over whether the cessation must also be irreversible, physicians should not be required to participate in DCD. Because the preparation for organ recovery in DCD begins before the declaration of death, there are potential conflicts between the donor’s and recipient’s interests. These conflicts can be managed in a variety of ways, including informed consent and separating the various participants’ roles. For example, informed consent should be sought for pre-mortem interventions to improve organ viability, and organ procurement organization personnel and members of the transplant team should not be involved in the discontinuation of life-sustaining treatment or the declaration of death. It is also important to emphasize that potential donors in cases of DCD should receive integrated interdisciplinary palliative care, including sedation and analgesia. *Pediatrics* 2013;131:1021–1026

INTRODUCTION

The persistent mismatch between the supply of and need for transplantable organs and the resulting deaths of individuals on the waiting list have led to a variety of efforts to increase the supply. As of May 17, 2012, there were 878 individuals aged <18 years awaiting a kidney transplant and 513 awaiting a liver transplant. In 2011, 10 individuals aged <18 years died while waiting for a kidney transplant, and 20 children and adolescents died while waiting for a liver transplant.¹ One effort to increase the supply of transplantable organs has been renewed interest in donation after circulatory death (DCD), which is the retrieval of organs from individuals declared dead after the irreversible cessation of circulatory and respiratory functions. (This

process was initially referred to as “nonheartbeating organ donation” and then as “donation after cardiac death.” The most recent change in terminology emphasizes that the determination of death is based on the cessation of circulatory, not cardiac, functions.²) There are several forms of DCD, and the current statement focuses on “controlled” DCD: the recovery of organs after the planned withdrawal of life-sustaining medical treatment.³

Although DCD was the initial form of deceased organ donation, it was eclipsed by recovery of organs from individuals declared dead according to neurologic criteria after these criteria were established and evidence showed improved graft function from such donors. There was renewed interest in DCD in the 1990s, including the publication of the so-called Pittsburgh Protocol,^{4,5} given the persistent shortage of transplantable organs. Recent estimates suggest that DCD could increase the supply of transplantable organs by 20%.⁶ A number of subsequent reports and consensus statements have addressed points of controversy, such as the waiting period before the declaration of death and the use of pre-mortem interventions to improve graft function.^{7–10} More recent pediatric studies reporting similar graft survival in kidneys and livers from donors declared dead according to neurologic and cardiovascular criteria have further increased interest in DCD.¹¹

Increased acceptance of DCD has resulted in regulatory oversight. The Joint Commission mandates that, although hospitals need not perform DCD, their policies must address it.¹² The United Network for Organ Sharing has articulated Model Elements for Controlled DCD Recovery Protocols¹³ and requires its member hospitals to perform solid organ transplants

to develop protocols which address the required elements to facilitate the recovery of organs from donors in cases of DCD.¹⁴ The Organ Donation Breakthrough Collaborative has also established the goal of having donors in DCD cases represent 10% of all organ donors.¹⁵

The current policy statement addresses the 2 major conceptual and ethical issues related to DCD: when can organ recovery begin, and how should conflicts of interests be managed? It provides greater detail than the American Academy of Pediatrics’ policy statement “Pediatric Organ Donation and Transplantation,”¹⁶ but it does not address general issues, such as medical examiner release of organs. Discussing these issues is particularly important given the variation among DCD policies at children’s hospitals.¹⁷ Standards must be met to maintain the integrity of and public confidence in the organ transplantation system.

DECLARATION OF DEATH

Whether and when donors in DCD cases are dead is important because cadaveric organ transplantation operates under the “dead donor rule.” This rule can be characterized in 2 different ways, each with its own ethical justification. One version is that organ recovery must not cause the donor’s death. This version is justified by the prohibition against the direct killing of innocent persons. The other version is that the donor must be dead before the recovery of vital organs. This version is based on preventing potential negative outcomes, such as the mistreatment of potential donors and the erosion of public confidence in transplantation.¹⁸

Some commentators have recommended abandoning the dead donor rule. Miller and Truog,¹⁹ for example, argue that withdrawing life-sustaining

treatment causes patients’ death and that there is no ethical bright line between withdrawing life-sustaining treatment and active euthanasia. They contend that patients or their surrogates, who have previously decided to have life-sustaining medical treatment withdrawn, should be permitted to consent to the pre-mortem recovery of vital organs. Although they do not discuss the implications of their position for pediatrics, it would, in principle, extend to parents or guardians and capacitated adolescents or their proxies. Miller and Truog’s arguments are not, however, compelling. For example, they conflate patients’ right to refuse treatment with the distinction between killing and letting die. They also ignore well-developed arguments that the intentional killing of innocent persons is unethical and that the ethically relevant distinction is between different forms of letting die. The dead donor rule should, therefore, be retained, not only because the reasons supporting it are compelling but also because the reasons for abandoning it are insufficient.

The discussion of death commonly distinguishes definition, criteria, and tests. The predominant definition of death is “the cessation of functioning of the organism as a whole.”²⁰ This definition focuses on the functions possessed by the whole organism, such as consciousness and control of circulation, respiration, and temperature, rather than the functions of its constituent parts. Although the definition states the necessary and jointly sufficient conditions for correctly applying the concept of death, the criteria specify measurable conditions, and physicians use the tests to evaluate the criteria at the bedside. The 2 criteria for death are the neurologic and the cardiorespiratory.

Drawing an analogy to the declaration of death in other clinical contexts,

proponents of DCD argue that the cessation of circulatory function must be permanent but not irreversible. The cessation is permanent if it will not resume on its own through autoresuscitation or as a result of external action, such as cardiopulmonary resuscitation. Once sufficient time has elapsed to preclude the spontaneous recovery of circulatory function, it is permanent, because, as part of the decision to withdraw life-sustaining treatment, the parents or guardians previously decided to forego cardiopulmonary resuscitation. Irreversibility further requires that the function is incapable, within the limits of current technology, of being restored. Proponents of DCD contend that irreversibility is not necessary for the declaration of death.²¹ Numerous professional organizations and consensus groups support this argument.^{8–10}

Within this framework, how much time must elapse to preclude autoresuscitation sufficiently is a significant concern. Despite calls for additional research, data are limited on this topic. On the basis of narrative reviews, commentators have recommended waiting at least 2 minutes and not more than 5 minutes.^{8–10} The authors of the most recent systematic review, noting the low quality and limited scope of reports, concluded there are no cases of autoresuscitation without cardiopulmonary resuscitation.²² Until a large observational study that provides narrow confidence intervals around the duration of autoresuscitation is conducted, this timing remains a prudent judgment. Once death is declared, there is no need for an additional waiting period before the initiation of organ recovery efforts.

Declaring death requires tests in addition to definitions and criteria. It would be prudent to use more sensitive and/or objective tests when they

are available. For example, using indwelling arterial catheters, Doppler ultrasonography, or echocardiography may be preferable to palpating pulses or auscultating heartbeats.²

There are, however, 2 significant criticisms of the proponents of DCD's arguments. One objection is that irreversibility is a necessary criterion for the declaration of death. Although permanence and irreversibility are causally related (ie, without intervention, permanent cessation will become irreversible), they are not contemporaneous. During the time between when circulatory function is permanently lost and when it is irreversibly lost, critics argue, individuals are dying but not yet dead.²³ This objection can also be stated in terms of the relationship between the cardiorespiratory and neurologic criteria of death. Rather than being independent criteria, the neurologic criteria are arguably fundamental. Although individuals who fulfill the cardiorespiratory criteria inevitably fulfill the neurologic criteria, if resuscitation is withheld, additional time must elapse. A second criticism is that replacing irreversibility with permanence inappropriately makes the declaration of death contingent on the intent and action of others rather than an intrinsic condition of the organism.²³ Nevertheless, the criticism that retrieving vital organs from donors in DCD cases is the proximate cause of death is not sound. If sufficient time passes to preclude autoresuscitation, progressive hypoxia-ischemia of the central nervous system is the proximate cause of death.²⁴

Although the need to increase the supply of transplantable organs is compelling and the arguments for the sufficiency of permanence for declaring death are widely accepted, the criticisms of these arguments are sufficient that physicians should not be

required to retrieve organs from donors in cases of DCD.²⁵ Institutions have an obligation to provide patients and their families access to DCD. Whether institutions themselves should be able to refuse to perform DCD is ethically controversial because of burdens placed on patients and their families by alternatives, such as the transfer of patients to other institutions.²⁶ The American Academy of Pediatrics could not reach consensus on whether institutions may refuse to participate.

Recent publications have highlighted related conceptual and practical issues. In 2008, Boucek et al²⁷ reported successfully transplanting hearts from 3 infant donors in cases of DCD. Some criticized the waiting period of 75 seconds in 2 of the transplants as being too short. Shortening the waiting period is particularly problematic in infants because they were not part of the population in which autoresuscitation was studied, and their organs may be more resilient.² Others contended that the resumption of cardiac activity in the recipient negates the determination of death.²⁸ The current definition of death focuses on the loss of integrated functioning of the organism that is demonstrated by the absence of autoresuscitation. Residual function of individual organs and tissues is consistent with death of the organism as a whole.

Others have reported on the use of extracorporeal membrane oxygenation (ECMO) in donors to support organ perfusion between the declaration of death and organ recovery and, thereby, improve outcomes in the transplanted organs.^{29,30} ECMO was originally designed to provide cardiorespiratory support to individuals with reversible cardiorespiratory failure. The use of ECMO in DCD is problematic because it artificially replaces circulatory function analogous to a

ventilator in patients with severe brainstem or spinal cord injuries. The additional concern is that reperfusion of the brain could restore consciousness. A potential modification is to prevent perfusion of the brain or organs above the diaphragm.² It is not clear whether these measures are sufficient to permit donors to be declared dead according to the cardiorespiratory criteria or whether donors receiving ECMO should be evaluated by using the neurologic criteria.

CONFLICTS OF INTERESTS

In addition to conceptual and practical issues regarding the declaration of death, DCD involves a variety of conflicts of interests.³¹ In contrast to donors declared dead according to the neurologic criteria, preparation for organ recovery efforts in DCD begins before the declaration of death. This preparation may include premortem interventions, such as placing lines or administering heparin, and modifications of the usual process of withdrawing life-sustaining treatment. These actions create the potential for conflicts between the interests of the donor and of the recipients.

These potential conflicts are exacerbated by the need to limit warm, and to a lesser extent cold, ischemic time. Organs tolerate oxygen deprivation better at colder temperatures than at warm ones. In “brain-dead” donors, the organs are relatively normally perfused before recovery and then rapidly cooled. In donors in cases of DCD, organs may experience hypoperfusion during the time between stopping life-sustaining treatment and recovering and cooling the organs. This hypoperfusion may damage the organs and impair their function. Premortem practices are altered in DCD to diminish warm ischemia times, and the maximum duration of organ recovery efforts is frequently stipulated.

(The fact that donation efforts will cease if the potential donor does not die within the specified time period should be disclosed as part of the informed consent process.)

The donor’s informed consent is a potential way to manage the conflicts of interests. Capacitated adults can accept the risks involved in the donation process to benefit potential recipients. Informed consent by the donor is, however, unlikely in DCD. Most potential donors in cases of DCD have suffered serious, irreversible neurologic injuries and are incapacitated. Expressing one’s interest in donation (eg, by signing a donor card) does not currently constitute informed consent for the modifications in premortem management required by DCD.³²

Parents or guardians “consenting” for their children further complicate the issue. In contrast to surrogate decision makers for previously capacitated adults who should make decisions on the basis of substituted judgment, parents or guardians should make decisions based on their child’s and family’s interests. Giving permission for their child to become an organ donor may permit families to create meaning or value in a tragic circumstance. Changes in premortem treatment may create conflicts between the interests of the recipient and/or the family and the interests of the donor. Minimally, changes in premortem treatment should not be contrary to the donor’s interests.

The potential for conflicts arises at multiple points in the donation process, including consent to organ donation, premortem interventions to promote organ viability, palliative care, and declaration of death.

- The decision to withdraw life-sustaining medical treatment should be separate or decoupled from the decision to attempt to donate organs.^{7–10} The conceptual separation

of the issues can be reinforced by separating when the decisions are discussed and who participates in the discussions. This separation should be maintained, to the extent possible, if parents or guardians raise the issue of organ donation before deciding to withdraw life-sustaining medical treatment.

- Premortem interventions to improve organ viability should not harm the donor and require informed consent.^{7,9,10} Premortem interventions may include medications, such as anticoagulants or vasodilators, and procedures, such as line placement. Most of these interventions are neutral to patients’ interests. There is legitimate disagreement about whether anticoagulants may, in uncommon situations, contribute to the potential donor’s death and whether the pain of line placement constitutes a relevant harm.⁷ Parental permission is necessary for any premortem intervention to improve organ viability.
- Potential donors in cases of DCD should receive integrated interdisciplinary palliative care,³³ including sedation and analgesia.^{8,9} In DCD, palliative care occurs concurrently with preliminary organ donation efforts. Efforts should be made to limit alterations in the process of withdrawing life-sustaining treatment, such as its location. Alterations in the process of withdrawing life-sustaining treatment to reduce warm ischemia times should also be disclosed as part of the informed consent process. Medications should not be used with the direct intention of controlling the time of death.^{7,8,10}
- Although organ procurement organization personnel may be involved in evaluating potential donors and scheduling, they and members of the transplant team should not be

involved in the decision to withdraw life-sustaining treatment or its actual discontinuation. Programs should consider whether physicians caring for potential recipients should also be excluded from involvement in premortem management. If there are no alternatives to members of the transplant team participating in premortem interventions, such as prepping and draping and/or line placement, they should physically leave the patient care area before the withdrawal of life-sustaining treatment.^{7,10}

- As discussed previously, death should be declared by using relatively sensitive and objective tests. Organ procurement organization and transplant personnel should not be involved in the declaration of death. Programs should consider the appropriate role, if any, of those caring for potential recipients.^{7–10}

Institutions should have policies regarding these issues and periodically review performance to promote adherence. Ethics committees can contribute to the development of policies and the resolution of dilemmas or conflicts in their implementation.

RECOMMENDATIONS

- The American Academy of Pediatrics considers DCD an ethically acceptable option when practiced

within appropriate constraints, such as waiting a reasonable amount of time after the initial fulfillment of the cardiorespiratory criteria for death to preclude autoresuscitation before declaring death. On the basis of current evidence, the recommendation to wait between 2 and 5 minutes is reasonable.

- Additional research to better understand the phenomenon of autoresuscitation in infants and children should be conducted.
- Given legitimate ethical disagreement regarding the interpretation of the cardiorespiratory criteria for death, individual physicians should not be required to participate in DCD. Institutions should, nonetheless, provide access to DCD.
- Physicians should help institutions develop policies to manage the conflicts of interests inherent in the DCD process. Such policies should include:
 - the separation or decoupling of the decision to withdraw life-sustaining treatment from the decision to donate;
 - the prohibition of premortem interventions to improve organ viability that harm the patient;
 - the requirement of parental permission for acceptable premortem interventions;

- the provision of integrated interdisciplinary palliative care; and
- the prohibition of organ procurement organization staff and transplant team members from participating in the discontinuation of life-sustaining treatment or the declaration of death.

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Pediatrics 2013;131;1021

DOI: 10.1542/peds.2013-0672 originally published online April 29, 2013;

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Pediatrics 2013;131;1021

DOI: 10.1542/peds.2013-0672 originally published online April 29, 2013;

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