

Sample Policy for Organ Donation after Cardiac Death

This document has been developed by the ASA Committee on Transplant Anesthesia and the Committee on Critical Care Medicine in conjunction with the American Society of Critical Care Anesthesiologists in response to anesthesiologists who have asked for advice regarding their role in donation after cardiac death (DCD) organ recovery. This sample policy has been reviewed by the ASA Committee on Ethics and the Committee on Critical Care Medicine but has not yet been approved as a practice parameter or policy statement by the ASA House of Delegates. This sample policy is intended to serve as an educational guide and possible template for DCD organ recovery and transplantation policies that should be customized by any department or institution choosing to use it. Periodic review and revision of policies and procedures by clinicians, administration and legal representatives are warranted in keeping with the advances in technology and practice, in particular studies focused on identification and management of appropriate DCD donors. This document is a sample policy and practice may vary based on sound clinical judgment of the responsible anesthesiologist and on the institution's policies and applicable laws and regulations.

The concept of DCD has generated significant controversy, ethical concern, and emotional backlash in the public sector over the past decade. As such, most healthcare policy groups and professional medical associations have studied the question of DCD with the overwhelming majority supporting a statement from the Institute of Medicine (1997) that determined donation after cardiac death to be "a medically effective and ethically acceptable way to reduce the gap between the supply and demand for donor organs". Current practice was discussed by participants of the National Conference on DCD held in Philadelphia in 2005. Subsequent expansion of the practice of DCD has resulted from active support of the Organ Donation and Transplantation Breakthrough Collaborative and new Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements that institutions develop and implement standardized DCD policy.

Introduction

The practice of DCD involves the continuum of quality end-of-life care for patients and their families and withdrawal of treatments that are not beneficial. Withdrawal of life support is not within the expertise of practice of all anesthesiologists. Optimally, patients presenting for organ donation after cardiac death should receive care from their own primary care physician and/or the attending of record who has established rapport with the patient, family, and/or agent. "Agent" means an individual authorized to make health-care decisions on the principal's behalf by a power of attorney for health care; or expressly authorized to make an anatomical gift on the principal's behalf by any other

record signed by the principal.

Anesthesiologists are the natural leaders and facilitators in the operating room and as such, should be knowledgeable and informed of the major practical and ethical issues surrounding DCD and organ retrieval. Anesthesiologists should help to develop protocols within their own hospitals for provision of ethical terminal care for organ donor patients and their families, with the assistance of guidelines developed by the Institute of Medicine and the United Network for Organ Sharing (UNOS). Anesthesiologists should be respectful of the wishes of donor patients, their families, and their primary care physicians when they are in the operating room setting, but anesthesiologists should not be required to administer care to these patients.

What is Donation after Cardiac Death (DCD)?

The President's Commission on Death Determination supports two separate, but complementary sets of criteria. One is based on irreversible absence of circulation and respiration (Donation after Cardiac Death, DCD), and the other is based on irreversible absence of whole brain function (Donation after Brain Death, DBD). Either is satisfactory for the determination of death before organ donation.

The Uniform Determination of Death Act

The National Conference of Commissioners on Uniform State Laws in 1980 formulated the Uniform Determination of Death Act (UDDA).

The UDDA states that: "An individual is dead who has sustained either

- (1) irreversible cessation of circulatory and respiratory functions, or
- (2) irreversible cessation of all functions of the entire brain, including the brain stem"

A determination of death must be made in accordance with accepted medical standards. This definition was approved by the American Medical Association in 1980 and by the American Bar Association in 1981.

DCD is an ethically acceptable practice and capable of increasing the number of deceased-donor organs available for successful transplantation. Most patients considered for DCD will have been in the intensive care unit (ICU) and are fully dependent on ventilatory and circulatory support. A decision to forgo/withdraw further life sustaining therapies will have been made in accordance with the patient's wishes and legal healthcare proxy before and independent of any discussions about DCD. Most, but not all of these patients, will be neurologically devastated, but do not meet criteria for whole brain death. DCD donor death occurs when respiration and circulation have ceased and cardiopulmonary function will not resume spontaneously. Electrocardiographic (ECG) silence is not required for the determination of death, because the criterion for determining death is the absence of circulation. The period of observation necessary to determine that circulation will not recur spontaneously after removal of life sustaining therapies has been reviewed by many organizations. Guidelines require waiting for

greater than 2 minutes but no more than 5 minutes of pulselessness before pronouncing a patient dead in the context of DCD. This 2 to 5 minute time interval takes into consideration that there is no evidence in the literature of “auto-resuscitation” of the heart following 2 minutes of cardiac arrest and observing an end-point of 5 minutes will minimize warm ischemic damage to perfusable organs. This practice is in accordance with recommendations from the Institute of Medicine, the American College of Critical Care Medicine/Society of CCM and the Canadian Council on Organ Donation.

How is irreversibility defined?

Irreversibility is recognized by persistent cessation of function during an appropriate period of observation. Based on a cardiopulmonary criterion, DCD donor death occurs when respiration and circulation have ceased and cardiopulmonary function *will not resume spontaneously*. This meaning of “irreversibility” also has been called the “permanent” cessation of respiration and circulation.

In clinical situations in which death is expected, once respiration and circulation cease (irrespective of electrical cardiac activity), the period of observation necessary to determine that circulation will not recur spontaneously (autoresuscitation) may be only a few minutes. Current data on autoresuscitation indicate that the relevant event is cessation of circulation, not cessation of electrical activity.

When life-sustaining therapy is withdrawn, based on the limited data available, spontaneous circulation does not return after 2 minutes of cessation of circulation.

How is the permanent absence of circulation determined?

Cessation of functions is recognized by an appropriate clinical examination that reveals the absence of responsiveness, heart sounds, pulse and respiratory efforts.

In applying the circulatory criterion of death in non-DCD circumstances, clinical examination alone may be sufficient to determine cessation of circulatory and respiratory functions. However, the urgent time constraints of DCD may require more definitive proof of cessation of these functions by the use of confirmatory tests. Confirmatory tests (e.g. intra-arterial monitoring or Doppler study) should be performed in accordance with the hospital protocol to assure the family and the hospital professional staff that the patient is dead.

Ethically and legally, DCD is not equivalent to DBD. Brain dead patients are by definition not conscious and not suffering. UNOS guidelines for maintaining perfusion of organs in patients with brain death are well established. In contrast, a DCD potential donor is still completing the dying process. Thus, quality end-of-life care is the absolute priority and must not be compromised by the donation process. Patients have the right to and should be provided medications that prevent and alleviate pain and suffering (“comfort care”), but no medication should be given, which is intended to hasten the patient’s death.

Principles for Institutional Development of DCD Guidelines

When a consensual decision has been made to withdraw life support, the routine opportunity for DCD should be available to honor a donor's wishes in every donor service area of the United States. As of January 1, 2007, it is a JCAHO requirement for hospitals to have and implement a DCD policy with direction from the regional Organ Procurement Organization (OPO).

The main principles for institutional DCD guidelines include the following:

- 1) Donor care and end-of-life decisions are paramount and determined by the intensivist or primary care physician and patient or their agent and potentially the hospital ethics committee;
- 2) All decisions and actions taken following the decision to consider a patient for DCD should preserve the legal limits of patient autonomy, which refers to the capability and right of patients to control the course of their own medical treatment and participate in the treatment decision-making process through informed consent.
- 3) It is ethically reasonable for pediatric DCD to occur. However, children (especially those under the age of 14) represent a special case in organ donation because they have never achieved sufficient capacity to choose for themselves. All decisions about their care are made by guardians based upon best interest of the minor and not based upon preservation of patient autonomy per se.
- 4) Conditions of DCD eligibility should be established;
- 5) The decision for withdrawal of ICU treatments must be made before and separate from any discussion and decision to donate organs; one of the ethical axioms of organ donation necessitates adherence to the dead donor rule, “the retrieval of organs for transplantation should not cause the death of a donor”;
- 6) The patient’s intensivist or primary care physician of record is best suited to withdraw unwanted or futile treatments, prevent potential suffering throughout this process and should be welcomed into the operating room; the patient’s intensivist/physician should declare and record the time of death; in order to avoid the appearance of conflict of priorities, the physicians caring for a donor should not be involved in any of the donation, organ procurement or transplantation procedures. In order to avoid potential conflict of interest, it would be optimal that participation of the intensivist in withdrawal of unwanted or futile care should be avoided if the intensivist is to participate in the “planned” care of the recipient.
- 7) Determination of death is made by cardiopulmonary criteria; the period of circulatory cessation and the monitoring modality that confirms death is institution specific; declaration of death should be legally binding according to state requirements.

Protocols for DCD organ recovery may include the pre-recovery administration of anticoagulants, vasodilators, antioxidants and drugs designed to minimize ischemia-reperfusion injury and preserve vascular endothelium. Inadequate data mean that optimal

timing of administration of these drugs during the DCD process is not known. It is mandatory that any drug therapy must be intended to benefit the patient, not hasten the death of the donor (double effect).

The administration of heparin at the time of withdrawal of life-sustaining treatment is the current standard of care. The long-term survival of the transplanted organs may be at risk if thrombi impede circulation to the organ after reperfusion. Most transplant centers specify the timing of heparin administration in DCD, and omission of heparin may hinder the distribution of recovered organs. The use of heparin is considered controversial on the basis of theoretical concerns that it may hasten the death of the donor by causing intracranial hemorrhage or worsening active bleeding. Nevertheless, there are no reported cases illustrating that the administration of heparin causes sufficient bleeding after withdrawal of treatment to cause death of the donor.

Rapid postmortem core cooling of perfusable organs with preservation solutions is essential to limit the warm ischemic insult. Informed consent of the patient or agent is necessary for any premortem cannulation of large arteries and veins or any other medical interventions to support the organs for donation prior to death.

Model Elements for Controlled* Donation after Cardiac Death Policy

1. Suitable Candidate Selection
 - a. A patient who has a non-recoverable and irreversible neurological injury resulting in ventilator dependency but not fulfilling brain death criteria may be a suitable candidate for DCD.
 - b. Other conditions that may lead to consideration of DCD eligibility include end stage musculoskeletal disease, pulmonary disease, and high spinal cord injury.
 - c. The decision to withdraw life sustaining measures must be made by the patient care team, legal next of kin, or agent and documented in the patient's chart.
 - d. The assessment for DCD candidate suitability should be conducted in collaboration with the local OPO (Organ Procurement Organization) and the patient's primary health care team.
 - e. The intensivist or the primary care physician should raise the possibility of organ donation and the OPO personnel obtains consent for the donation thereby reinforcing in practice the separation between the role of the primary care team and the OPO.
 - f. An assessment should be made as to whether death is likely to occur (after the withdrawal of life sustaining measures) within a time frame that allows for organ donation (usually 60 to 120 minutes).

2. Informed Consent

- a. Informed consent for organ donation is obtained from the appropriate person or entity according to jurisdictional policy after the decision to withdraw life-sustaining measures is obtained. A Do Not Resuscitate (DNR) order is entered into the patient's chart.
- b. Informed consent is required for any pre-recovery procedures or drug administration specific for the purposes of organ donation (anticoagulants, vasodilators, antioxidants, cannulation of the femoral vessels, chest incision, lymph node excision, bronchoscopy). Institutional policy will dictate whether the OPO or the primary care physician obtains consent for these procedures from the family.
- c. Clearance from medical examiner/coroner must be obtained when applicable.
- d. Location (ICU, OR or other) for the process of withdrawal of life-supporting measures should be determined after discussion and agreement with the donor's family or agent.
- e. There should be a plan for patient care if death does not occur within the established timeframe after the withdrawal of life sustaining measures. This plan should include logistics and provisions for continued end of life care and be discussed with the family and/or agent.
- f. If the patient/DCD donor at any time meets brain death criteria, established UNOS policy and procedure for DBD donors should be implemented.

3. Patient Management

- a. No member of the Transplant Team or OPO staff may participate in the guidance or administration of palliative care, or the declaration of death.
- b. End-of-life care is the responsibility of the patient's intensivist or primary care physician. Patients have the right to and should be provided medications that prevent and alleviate pain and suffering (comfort care). Patients may require anticipatory dosing with analgesics, sedatives and/or amnestics prior to extubation and may require additional medication administered as necessary, titrated to the observed level of distress. Any medication must be given according to need and with the goal of alleviating any pain and suffering, not with the intention of hastening the dying process.
- c. Laboratory studies are needed to evaluate donor suitability.
- d. If indicated and consent is obtained, a bronchoscopy may be performed prior to withdrawal of support and extubation to determine suitability of the lungs for donation; at some centers, bronchoscopy may be performed after declaration of death; recommendations for ventilator settings and FiO₂ both prior to withdrawal and after reintubation may be specified.
- e. There must be a determination of the location and process for withdrawal of life sustaining measures as a component of the patient's care. Considerable resources are required to provide optimum end-of-life patient care to implement a DCD protocol in the operating room. In

addition, the organ procurement surgery requires multiple personnel and healthcare resources. Communication between the OPO and all others involved in the DCD process and management of the operating room is essential for the success and optimal timing of implementing the DCD process.

4. Withdrawal of Life Sustaining Measures

- a. For transport to the operating room the patient remains monitored and ventilated as appropriate.
- b. The patient's intensivist or primary care physician has expertise in the withdrawal of life support, voluntarily agrees to participate in the withdrawal of life support, and will not be involved in organ retrieval or the intraoperative care of the recipients of this patient's donated organs.
- c. Institutional guidelines for withdrawal of life support and quality end-of-life care should specify if the patient is to be extubated, which involves removing the endotracheal tube.
- d. Family logistics: It is ideal to withdraw life sustaining measures in the OR with the family present; practical issues related to accomplishing this include the presence of immediate or extended family, escort procedure, and attire, and the wishes of the family.
- e. The operating room personnel involved with the retrieval or transplantation of organs must not be present or visible to the family when withdrawal of life sustaining measures is occurring.

5. Declaration of Death

- a. The patient care team member that is authorized to declare death must not be a member of the OPO or Transplant team.
- b. The method of declaring cardiac death must fulfill the legal definition of death by an irreversible cessation of circulatory and respiratory functions **before** the pronouncement of death.
- c. Declaration of death is made following an observation period recommended to be at least two minutes and not more than 5 minutes.
- d. Death must be certified using standardized, objective and auditable criteria, and must follow state law.
- e. Depending on institutional policy, if informed consent is obtained for pre-mortem isolation or cannulation of femoral vessels, these procedures are usually performed prior to the family entering the operating room. The transplant team must exit the operating room prior to the family entering. After death, the family must be escorted out of the operating room before the surgical transplant teams enter the room. Families should be told that they will be rapidly escorted out after death for purposes of preserving the donated organs. The transplant team must not be present in the operating room during withdrawal of care. The transplant team should be permitted no contact with the patient until after the intensivist or primary care physician has declared the patient dead and the written documentation has been completed.

- f. In the event that death has not occurred within one hour after termination of life sustaining measures, the patient should be reassessed; a decision is then made to either extend the waiting period for an additional hour or cease the donation process in which case the medical team transports the patient from the operating room to a predetermined location.

6. Organ Recovery

- a. If applicable, placement of femoral cannulas and administration of pharmacologic agents (ie: regitine, heparin) for the sole purpose of donor organ function must be detailed in the consent for donation process.
- b. Once death is documented, the donor's lungs will require re-inflation if they are being considered for retrieval. This will necessitate intubation of the donor. The OPO should be responsible for coordinating these efforts by designating a member of the transplant team for re-intubation or providing an alternate individual (as per institutional DCD protocol).
- c. Once there is a declaration of death, an incision to recover organs should be performed immediately. The transplant surgeons will initiate perfusion of the organs with cold preservation solution and proceed with the donor operation.

7. Financial Considerations

- a. OPO policy should ensure that no donation related charges are passed to the donor's family.

8. Conflict of Interest Safeguards

- a. The physician who declares death must not be involved in the procurement or transplantation of donor organs.

*Maastricht Classification- Definition of Controlled DCD Donors

DCD donors are grouped by the Maastricht classification (1995; amended 2003):

- I Dead on arrival to hospital
- II Unsuccessful resuscitation
- III Awaiting cardiac arrest – In-patient (withdrawal of support)
- IV Cardiac arrest after brain-stem death
- V Cardiac arrest in a hospital inpatient

Controlled DCD donors would include those outlined in classification III of the Maastricht criteria.

The Non-Critical Care Anesthesiologist's Role with DCD and Policy

It is important that anesthesiologists become involved with the development of their institutional DCD protocol and be familiar with their protocol including the following key points:

- a. Continuity of care for patients presenting for DCD should optimally be provided by the donor patient's own primary care physician and/or intensivist. The responsibility for withdrawal of life support of the DCD patient also belongs to this individual and should never be transferred to anyone other than a qualified physician who has a preexisting treating relationship with the patient and expertise in end-of-life care. Provision of quality end-of-life care for DCD patients and their families is the absolute priority and must not be compromised by the donation process. Managing the withdrawal of life sustaining treatments may not be within the expertise or practice of all anesthesiologists. For DCD, determination of death is made using cardiopulmonary criteria and does not require evidence of irreversible brain injury (the criteria for donation after brain death, or DBD).
- b. While anesthesiologists who manage operating rooms should not be required to participate in the DCD process, they are strongly encouraged to be familiar with the DCD protocols particular to their institution, to determine appropriate methods for trafficking of medical personnel and donor families, as well as issues related to timing, communication, and arrangements for care outside the operating room if needed.

Respect for the Potential DCD Donor, DCD Donor, and Families

The death of a patient and donation of their organs should be recognized as a gift that a patient and/or their families are offering to others. All personnel should be respectful of the wishes and privacy of the donor patients and their families, and all those involved in the donation and transplantation process. All should strive to facilitate the donation and transplantation process, mindful of their responsibilities, particular expertise, potential conflicts of interest, and according to the guidelines listed above, institutional policies, and state and federal laws.