

Statement on Controlled Organ Donation After Circulatory Death

Committees of Origin: Critical Care Medicine, Ethics and Transplant Anesthesia

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This statement has been developed as a result of collaboration between the American Society of Anesthesiologists (ASA) Committees on Transplant Anesthesia, Critical Care Medicine, and Ethics. The Society of Critical Care Anesthesiologists supports this statement.

While the concept of organ donation after circulatory death (DCD) has previously generated controversy and concern, clearly written policies aided the development of standardized practice, resolved uncertainties and continue to be required by the Center for Medicare and Medicaid Services (CMS) and the Joint Commission. DCD contributed almost 9% of organs transplanted in 2015.¹ As such, the original statement from the Institute of Medicine (1997) has held true in that DCD is “a medically effective, and ethically acceptable approach to reducing the gap that exists now and will exist in the future between the demand for and the available supply of organs for transplantation”.²

The document is intended to serve as an educational guide and template for donation after circulatory death organ recovery and transplantation policies that should be customized by any department or institution choosing to use it. Changes in technology and practice require that such policies and procedures undergo periodic review and revision by clinicians, administration and legal representatives.

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 no longer beneficial or may extend suffering. Optimally, patients presenting for organ donation after circulatory death should receive care from their primary care/critical care attending physician or their designee who has established rapport with the patient, family, and/or agent. “Agent” means an individual authorized to make healthcare decisions on the patient’s behalf by a power of attorney for health care or authorized to make an anatomical gift on the patient’s behalf by any other record signed by the patient.

Institutions should develop a protocol for the provision of end-of-life care by appropriately skilled physicians. Withdrawal of life support is not within the expertise of practice of all anesthesiologists, and is not a common aspect of anesthesia practice within the operating room.

However, anesthesiologists are the natural leaders and facilitators in that environment and should be knowledgeable and informed of the major practical and ethical issues surrounding DCD and organ retrieval. Consequently, anesthesiologists should be involved in the development of protocols within their own hospitals for provision of ethical terminal care for organ donor patients and their families, informed by guidelines developed by the Institute of Medicine and the United Network for Organ Sharing (UNOS)^{3,4}. 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 no physician should be required to administer care to these patients.

DEFINITIONS

What is Circulatory Death?

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 Circulatory Death – DCD), and the other is based on irreversible absence of whole brain function (Donation after Death declared by Neurologic Criteria - DDNC).⁵ Either is satisfactory for the determination of death before organ donation, and both are supported in law.⁶

What is the Dead Donor Rule?

According to the dead donor rule, a patient should not be killed for or by the donation of their organs, and complete single organs should only be procured from dead people. Single lungs, kidneys and lobes of a liver may be donated by living donors in strictly regulated circumstances.

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) that states:

“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.”⁶

This definition was approved by the American Medical Association in 1980 and by the American Bar Association in 1981. All states within the United States of America adhere to the UDDA or some modification of that.

How is irreversibility defined?

Irreversibility is recognized by persistent cessation of function during an appropriate period of observation. Based on cardiopulmonary criterion, 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.

Electrocardiographic (ECG) silence is not required for the determination of death, as it may persist beyond the absence of circulatory activity (pulselessness) which is the criterion for declaring death.

Cessation of circulatory and respiratory 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 circumstances other than DCD, 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 hospital professional staff that the patient is dead.

There is an obligatory period of observation to determine that such circulatory activity will not spontaneously recur, and that subsequently death may be declared. In the context of DCD, guidelines require waiting for longer than two minutes but for no more than five minutes of absent circulatory function before pronouncing the patient dead.

This 2 to 5 minute time interval takes into consideration that there is no literature to support “auto-resuscitation” of the heart following two minutes of circulatory arrest, while observing an end-point of five minutes minimizes warm ischemic damage to perfusable organs. This is in accordance with recommendations from the Institute of Medicine³, the American College of Critical Care Medicine⁷, the Society of Critical Care Medicine⁷, and the Canadian Council on Organ Donation⁸.

What are the requirements for consideration of DCD?

Most patients considered for DCD will have been in the intensive care unit (ICU) and are dependent on ventilatory and circulatory support. Many, but not all of these patients, will be neurologically devastated but do not meet the requirements for death declared by neurologic criteria.

Ethically and legally, a patient deemed a potential DCD candidate is not equivalent to a patient declared dead by neurologic criteria – those latter are by definition not conscious or alive and cannot suffer. UNOS guidelines for maintaining perfusion of organs in such patients are well established.

In contrast, a *potential* DCD donor is still completing the dying process but has not yet been declared dead. Thus, quality end-of-life care remains the absolute priority and must not be compromised by the donation process. Patients have the right to and should be provided those medications that prevent and alleviate pain and suffering (“comfort care”), but no medication should be prescribed or administered with the express intention of hastening death.

A decision to allow death to occur by forgoing or withdrawing further life-sustaining therapies will have been made in accordance with the wishes of the patient and/or agent (as defined above). This must happen prior to and independent of any discussions about DCD.

The local organ procurement organization (OPO) will have been notified of the patient’s critical state in keeping with CMS Conditions of Participation (§482.45 A-0370, A-0371) prior to

discussions of withdrawal of life-sustaining treatments. The OPO cannot thereafter approach patients and/or agents until after the decision to withdraw supportive treatments has been made.

Principles for Institutional Development of DCD Guidelines

When a consensual decision has been made to withdraw life support, the 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 Joint Commission requirement for hospitals to have and implement a DCD policy with direction from the regional Organ Procurement Organization (OPO)⁹.

The main principles for institutional DCD guidelines include the following:

- 1) Donor care and end-of-life decisions are paramount and determined by the primary care attending physician/critical care attending 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) Donor designation is a documented, legally binding commitment by an individual to make an anatomical gift and, just like a will or testament, it can only be revoked by that individual. Presence on the donor registry therefore informs the clinical team and OPO of the desired disposition of organs after death, but does not in itself constitute an authority to affect the mode or manner of dying. It does, however, emphasize and reinforce the imperative towards timely and appropriate communication between clinicians and the OPO.
- 4) It is ethically reasonable for pediatric DCD to occur. The decision about participation in DCD will be made by the guardians on behalf of the minor.
- 5) Conditions of DCD eligibility should be established.
- 6) The decision for withdrawal of 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.
- 7) The patient's primary care /critical care attending physician or their designee is best suited to withdraw life-sustaining treatments, prevent potential suffering throughout this process and should be welcomed into the operating room. The patient's attending critical care physician/primary care physician or designee should declare and record the time of death. In order to avoid potential 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 primary care/critical care attending physician or designee in withdrawal of life-sustaining treatments should be avoided if that critical care physician is anticipated to participate in the "planned" care of the recipient.
- 8) End-of-life care for potential organ donors should satisfy the same standard as that of any patient undergoing withdrawal of life-sustaining treatments.
- 9) 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.

- 10) If the anesthesiologist is not involved in any procurement (including post-mortem intubation) or transplant procedures, they may by prior arrangement and mutual agreement substitute for the primary care/critical care attending physician in the declaration of death and patient management.

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. The optimal timing of administration of these drugs during the DCD process is not known.

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 presently no reported cases to suggest that the administration of heparin causes sufficient bleeding after withdrawal of treatment to hasten 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 Circulatory 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 the definition for death declared by neurologic 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. This must occur prior to any discussion of organ donation.
 - d. The assessment for DCD candidate suitability should be conducted in collaboration with the local OPO and the patient's primary health care team.
 - e. If queried, the healthcare team may direct questions regarding organ donation to OPO personnel or designated requestor, who will obtain 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 treatments) within a time frame that allows for organ donation (usually 60 to 120 minutes).

2. Informed Consent

- a. Authorization for organ donation is obtained from the appropriate person or entity according to jurisdictional policy after the decision to withdraw life-sustaining treatments 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 or agent.
- c. Clearance from the medical examiner/coroner must be obtained when applicable.
- d. Location (intensive care unit, operating room, or other) for the process of withdrawal of life-supporting treatments should be determined after discussion and agreement with the donor's family or agent.
- e. There should be a plan for patient care and immediate family support if death does not occur within the established timeframe after the withdrawal of life-sustaining treatments which precludes the planned organ procurement. This plan should include logistics and provisions for continued end-of-life care and be discussed with the family and/or agent, who should be educated as to the possibility of non-donation and subsequent management.
- f. If the patient/DCD donor at any time meets the definition of death declared by neurologic criteria, established UNOS policy and procedure for DDNC donors should be implemented.

3. Patient Management

- a. No member of the surgical procurement, transplant teams, or OPO staff may participate in the guidance or administration of end-of-life care, or the declaration of death.
- b. End-of-life care is the responsibility of the patient's primary care/critical care attending physician or their designee. 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 considered 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 the patient is to be extubated and the lungs are being considered for procurement, **the OPO should have discussed their requirements for reintubation and have made arrangements for patients who are known to have difficult airways with the attending anesthesiologist overseeing the operating room, well in advance of withdrawal of life-sustaining treatments. Alternatively, the OPO may provide an individual to perform this function (as per institutional DCD protocol). Whoever performs the reintubation of the patient's trachea should not be involved in the declaration of death.**
- e. 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 prior to withdrawal may be specified by the attending physician overseeing end-of life care. Ventilation after death will be dictated by OPO protocol.
- f. There must be a determination of the location and process for withdrawal of life-sustaining treatments 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 or chosen location (see above) the patient remains monitored and ventilated as appropriate.
 - b. The patient's primary care/critical care attending physician or their designee with expertise in the withdrawal of life support 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.
 - d. Family logistics: Ideally, families should be offered the opportunity to be present around the withdrawal of life-sustaining treatments. Practical issues related to accomplishing this in the operating room include the presence of immediate or extended family, escort procedure, 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 treatments 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 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 patient entering the operating room. The surgical procurement 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 procurement teams enter the room. Families should be told that they will be rapidly escorted out after death for purposes of preserving the donated organs. A member of staff should be identified in advance with the

- responsibility of escorting the family out of the operating room to an appropriate location. The surgical procurement team must not be present in the operating room during withdrawal of care. After any indicated and consented placement of premortem cannulae, the surgical procurement or transplant teams should have no contact with the patient until after the primary care/critical care attending physician or their designee 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 treatments, 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 and continues care of the patient. The member of staff tasked with escorting the family should accompany them back to that location.
6. Organ Recovery
- If applicable, antemortem placement of femoral cannulas and administration of pharmacologic agents for the sole purpose of donor organ function must be detailed in the consent for donation process.
 - Once death is documented, the donor's lungs will require reinflation if they are being considered for retrieval. This may necessitate reintubation of the donor. (See 3d above)
 - 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
- OPO policy should ensure that no donation related charges are passed to the donor's family.
8. Conflict of Interest Safeguards
- The physician who declares death must not be involved in the procurement or transplantation of donor organs.

**Maastricht Classification: Definition of Controlled DCD Donor*

DCD donors are grouped by the Maastricht classification (1995; amended 2000)¹⁰:

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| 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 and categories I, II, IV, and V are termed uncontrolled.¹¹

The 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:

- a. Continuity of care for patients presenting for DCD should optimally be provided by the donor patient's own primary care/critical care attending physician or their designee. 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 cessation of function of the whole brain (the criteria for DDNC).
- b. **While anesthesiologists staffing operating rooms should not be required to participate in withdrawal of care or declaration of death, they may be asked to reintubate and ventilate lungs to support and facilitate the DCD process. A role in reintubation would also preclude their involvement in antemortem procedures supporting the donation process, which should normally occur in the ICU prior to transfer to the operating room. Consequently, all anesthesiologists are strongly encouraged to be familiar with the DCD protocols particular to their institution, to determine appropriate methods for management of medical personnel and donor families, as well as 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.

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