

Organ Donation After Circulatory Death: Ethical Issues and International Practices

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Donation after circulatory death (DCD) is an increasingly utilized practice that can contribute to reducing the difference between the supply of organs and the demand for organs for transplantation. As the number of transplanted organs from DCD donors continues to increase, there is an essential need to address the ethical aspects of DCD in institutional DCD protocols and clinical practice. Ethical issues of respecting the end-of-life wishes of a potential donor, respecting a recipient's wishes, and addressing potential conflicts of interest are important considerations in developing policies and procedures for DCD programs. Although there may be diversity among DCD programs in Europe, Australia, Israel, China, the United States, and Canada, addressing ethical considerations in these DCD programs is essential to respect donors and recipients during the altruistic and generous act of organ donation. (Anesth Analg 2019;128:280–5)

It is 3 o'clock in the morning and you are the attending anesthesiologist on call at your hospital. A patient presents for controlled organ donation after circulatory death (controlled DCD). You are asked to extubate the patient, declare the patient dead, reintubate the patient, and provide care for the patient during organ procurement. Is it ethical for the same anesthesiologist to declare the patient dead and to participate in the organ procurement process? Is it ethical for the same anesthesiologist to declare the patient dead and reintubate the patient?

Despite the number of organ transplantations, there remains a shortage of donor organs. From January to December 2017, there were 34,770 transplants in the United States with 82.2% of these transplants from deceased donors and 17.8% from living donors.¹ Yet, in March 2018, there were almost 115,000 patients waiting for an organ transplant in the United States.² DCD is an increasingly utilized practice that can contribute to reducing the difference between the supply of organs and the demand for organs for transplantation. From 1993 to February 1, 2018, there were 16,043 DCD donors in the United States.³ In fact, the number of DCD donors more than doubled from 791 DCD donors in 2007 to 1883 donors in 2017.³ Furthermore, in 2017, 10.5% of transplanted organs were from DCD donors compared to 5.1% of transplanted organs being from donors after death declared by neurologic criteria (DDNC).⁴ As the number of transplanted organs from DCD donors continues to increase, there is an essential need to address the ethical aspects of DCD in institutional protocols and clinical practice.

DCD can occur in controlled or uncontrolled situations. Uncontrolled DCD may be a consideration, for example, with unsuccessful cardiopulmonary resuscitation resulting in a sudden unexpected death in an emergency room after a trauma. In contrast, with controlled DCD, the potential donor (eg, a patient with amyotrophic lateral sclerosis, a patient with a high spinal cord injury, or a terminally ill patient on a ventilator who does not meet criteria for DDNC) or surrogate decision-maker wishes to have life-sustaining treatment withdrawn. Once the decision is made to withdraw life-sustaining treatment, only then may organ donation be discussed. Death is declared before organ donation. Unlike uncontrolled DCD, controlled DCD involves planned or "controlled" circumstances. This manuscript focuses on the ethical issues of controlled DCD in adult patients as highlighted in the above-mentioned case.

The 4 principles of bioethics are integral in addressing the ethical issues of DCD. First and foremost, the autonomy of a patient must be respected. The principle of respecting a patient's autonomy encompasses disclosing information supporting a patient's choice with adequate understanding and supporting the patient's self-determination to make decisions based on the patient's own values/wishes without controlling influence from others.⁵ The ethical principle of beneficence (one should prevent and remove evil or harm and do or promote good) involves supporting the patient's wish to donate organs and the ethical principle of nonmaleficence (not to cause harm) is reflected in preventing pain and suffering of the donor.⁵ The fourth principle of bioethics is social justice—the fair distribution of benefits and burdens to all members of a society.⁵

Ethical issues of controlled DCD (as alluded to in the above-mentioned case) should be addressed by controlled DCD institutional and departmental protocols. First, the roles of individual health care team members must be delineated to prevent the risk of a conflict of interest between the interests of the potential DCD donor and the interests of the recipient. The physician who declares a patient dead must not participate in any organ procurement procedures, in the transplantation of organs, and/or in the care of the recipient.^{6–8} Second, the risks and benefits of organ procurement and transplantation as well as the disclosure of organ transplant outcomes of DCD programs should be discussed with recipients and potential DCD donors or surrogate decision-makers as applicable.⁹

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Considering organ transplant outcomes from DCD programs, the recipient may then make the autonomous decision to accept or refuse organs from DCD donors and the donor decision-maker may weigh the burdens versus potential benefits of DCD organ donation.⁹ Third, there must be respect for the **Dead Donor Rule**, which does not allow the procurement of organs from patients who are not declared dead and prohibits killing patients for organ procurement.¹⁰ A fourth ethical concern involves the principle of double effect in which an act that has an intended beneficial effect (relieving a patient's pain) must not be performed with the intention to cause an adverse effect (hastening death).¹¹ For example, end-of-life care for the potential donor may involve the administration of medications to alleviate discomfort without the intent to hasten the dying process. A fifth ethical issue to consider is that informed consent must be obtained and documented in the medical record for antemortem procedures performed on potential controlled DCD donors.⁶⁻⁸ Sixth, physicians whose values or religious beliefs do not align with the patient's wishes may recuse themselves from participating in the care of the patient. An alternative qualified physician is then sought to provide care for the patient. A seventh ethical issue is the respect for patients' autonomous wishes to donate their organs which is legally supported by the **US Uniform Anatomical Gift Act**.¹² Under the US Uniform Anatomical Gift Act, if an individual has designated his or her wish to donate organs in a will, advance directive, driver license, and/or donor registry, then the donation of his or her organs on death is legally binding and can only be modified by that individual.¹² An exception to this may be in the case of minors, whose parents or guardians may revoke the minor's decision to donate organs.¹² It is imperative that ethical issues are addressed in controlled DCD programs and recipients and donors are informed and respected throughout this altruistic process. Addressing ethical issues in controlled DCD will foster trust in the physician-patient relationship and in the relationship between physicians and families.

Policies and procedures for controlled DCD, as required by the Center for Medicare and Medicaid Services and the Joint Commission, should be developed and periodically reviewed by departments and institutions in collaboration with administration, legal experts, and health care team members including anesthesiologists.^{13,14} Considerations from the American Society of Anesthesiologists Statement on Controlled Organ Donation after Circulatory Death and the Institute of Medicine can be a resource to guide institutions in the development of their policies and procedures for controlled DCD and to address the ethical issues associated with DCD.⁶⁻⁸ An initial step in addressing ethical issues in the development of policies and procedures for controlled DCD includes delineating the roles of health care team members to prevent a perceived, actual, or potential conflict of interest of individual health care team members between the interests of the potential DCD donor and the recipient. The patient's primary care or intensive care unit attending physician provides care for the potential donor, which includes providing medications to ease pain and suffering without hastening death, declaring death and recording the time of death, and withdrawing life-sustaining therapy.⁶ To avoid further conflict of interest, this attending physician should not participate in any organ procurement procedures, in the

transplantation of organs, and/or in the care of the recipient.⁶⁻⁸ Another consideration is that before any discussion of organ donation, the withdrawal of life-sustaining therapy must be discussed and agreed on^{7,8} with documentation of this decision in the medical record.⁶ Specifically, the local organ procurement organization must not approach the patient or patient's family/surrogate decision-maker until the decision has been made to withdraw life-sustaining therapy.⁶ Once the decision is made to withdraw life-sustaining treatment and to proceed with controlled DCD, informed consent is obtained for the organ donation and for indicated procedures before the declaration of death (cannulation of vessels, administration of medications, bronchoscopy, etc).^{7,8} and a do not resuscitate order is documented in the medical record.⁶ End-of-life care for the potential donor is a priority, and the potential DCD donor should be provided medications to alleviate discomfort without the intent to hasten the dying process.^{6,15} After the performance of indicated antemortem procedures, the surgical team must leave the room until the patient is declared dead and written documentation is completed.⁶ The health care team participating in the procurement of donated organs and the team participating in the transplant of organs must not be visible to the family during the withdrawal of life-sustaining treatments.⁶

Under some circumstances, the lungs may be considered for procurement. In this situation, the organ procurement team may request that the donor patient be reintubated. Before the withdrawal of life-sustaining treatment, the organ procurement team must make prior arrangements with the anesthesiologist providing care for the operating room regarding reintubation of the patient's trachea especially for those patients who had a history of a difficult intubation.⁶ The practitioner who reintubates the patient's trachea should not participate in antemortem procedures and in the declaration of the patient's death.⁶ DCD policies and procedures may vary among institutions and departments. Delineating the roles of individual health care team members, respecting the end-of-life wishes of a potential donor, respecting a recipient's wishes, and addressing potential conflicts of interest are important considerations in developing policies and procedures of DCD programs.

With controlled DCD, declaration of death is made after the determination of irreversible circulatory and respiratory cessation¹⁶ by a physical examination that identifies the absence of a pulse, heart sounds, respiratory efforts, and responsiveness.¹⁵ The absence of electrocardiogram activity is not required for the declaration of death.¹⁷ Confirmatory tests (echocardiogram, intraarterial catheter pressure monitoring) may be required for more definitive proof and per institutional protocol.¹⁷ Furthermore, state law requirements and standardized and objective criteria must be met for the declaration of death.¹⁵ Recommended observation times from circulatory arrest to the declaration of death is at least 2 minutes and not >5 minutes, yet may vary in different countries and institutions.^{7,8,15,17,18} These recommended times reflect minimizing damage to organs and the lack of reports in the literature of autoresuscitation occurring after 2 minutes of circulatory arrest.¹⁵ If the patient does not die within a time frame (usually 1–2 hours) after the withdrawal of life-sustaining therapy,¹⁷ a plan should be made to provide end-of-life care for the patient.⁸ Before the DCD

process, the family or surrogate decision-maker should be appraised of the possibility of not being able to proceed with organ donation and the subsequent end-of-life care to be provided for the patient.

INTERNATIONAL DCD PROGRAMS

Although many international countries have DCD donors, there are some countries with legal restrictions to perform DCD. Furthermore, the availability of DCD, the protocols for DCD, the method of determination of death, the definition of the period of observation after circulatory arrest, and the duration of this observation period for DCD vary around the world.

Europe

In Europe, many but not all countries have DCD programs. For those European countries that have DCD programs, there is a **variation in the protocols** for DCD. In a study of DCD protocols in Europe, Wind et al¹⁸ obtained national and regional DCD protocols from national transplant societies and organ transplant coordinators. The authors found that in Italy, Austria, Latvia, and the Czech Republic, DCD is performed specifically at 1 or 2 hospitals, while **DCD** can be performed in **most hospitals** in the Netherlands and the **United Kingdom**.¹⁸ However, DCD is legally restricted in Finland, Germany, Greece, Bosnia-Herzegovina, Hungary, Lithuania, and Turkey.¹⁸ Those European countries with a protocol for organ donation also have an organ donation law.¹⁸ Of interest, the method of determination of death, the definition of the **period of observation after circulatory arrest**, and the duration of this observation period (**5 minutes in France** to **20 minutes in Italy**) differ among the European countries participating in DCD.¹⁸

Informed consent for DCD in European countries involves either an opt-in or opt-out registration system.¹⁸ With an **opt-in** registration system (eg, the Netherlands, the **United Kingdom**, and **Switzerland**), consent for DCD organ donation is confirmed by the potential donor having an organ donor card or being registered in a national registry.¹⁸ If there is a registered objection in the national registry, the organ donation will not proceed.¹⁸ However, in the **United Kingdom**, if a potential DCD donor has **registered** for organ donation, informed consent is **also obtained from the next of kin**.¹⁸ In the Netherlands, there is also an opt-in registration system, yet this system also includes 4 available choices. These 4 choices are the following: (1) donor with or without restrictions, (2) object to organ donation, (3) family to make the decision regarding organ donation, and (4) identification of a specific individual to decide on organ donation.¹⁹ With an **opt-out** registration system (eg, **Austria**, **Belgium**, **Czech Republic**, **France**, **Italy**, **Latvia**, and **Spain**), it is **presumed** that the potential DCD donor **has consented unless** the patient has **refused** to be an organ donor during his or her life.¹⁸ Thus, with **opt-out** registration, **consent** for DCD is **not required**. Some of these countries' DCD protocols also require the next of kin to give permission for the donation. For example, **Spain**, unlike **Austria** which does **not specify family consent in its protocol**, requires the next of kin to provide written permission for DCD.¹⁸ **Latvia** requires the next of kin to provide in writing their refusal to proceed with the

DCD if the potential donor did not register in the national registry.¹⁸

To address practitioners' potential conflicts of interest between the interests of the potential donor and recipient, Wind et al¹⁸ state that all European countries participating in DCD had a protocol in which 1 health care team member treated the patient and a different health care team member participated in the procurement of organs.

Australia

In Australia, the *National Protocol for Donation After Cardiac Death* was published in 2010 by the Australian Organ and Tissue Donation and Transplantation Authority.²⁰ DCD is governed by law throughout Australia and the specifics of the legislation in each State and Territory vary, including legislation regarding consent for organ donation and consent for antemortem interventions.²⁰

In some jurisdictions, consent for organ donation is required, and in other jurisdictions, the absence of a registered objection in the Australian Organ Donor Registration is required for organ donation.²⁰ If a patient has a registered objection to organ donation, organ donation cannot proceed. If a patient's declared wishes were to proceed with organ donation, there may be a situation in which the patient's family may not agree to have the patient's organs donated. In this situation, a discussion to understand the family's concerns is encouraged and the protocol supports not proceeding with the organ donation with the explanation that the patient may not have proceeded with the donation if he or she was aware of the distress organ donation would cause his or her family.²⁰ Before any discussion of organ donation, the withdrawal of life-sustaining therapy must be initially discussed and agreed on.²⁰ Antemortem procedures, performed to optimize the success of the transplanted organs, must be reviewed before proceeding to confirm that the procedures will not harm the patient or hasten the death of the patient.²⁰ Consent laws for antemortem procedures or administration of medications are not uniform in Australia and thus State and Territory legislation and institutional policies must be consulted.²⁰

The "Designated Officer" authorizes the organ donation and confirms consent for the organ donation (varies by State and Territory laws).²⁰ The term "Designated Officer" is used in all State and Territory legislation except in 1 area in which the phrase "the person in charge of the hospital" is used.²⁰ An Aboriginal Hospital Liaison Officer and/or Aboriginal Health worker provides support for Aboriginal families and health care team members.²⁰

The **Australia protocol** emphasizes the importance of **separating discussions, duties, and decisions** as DCD can cause **conflicts of interest** for the practitioner in terms of the interest of the potential donor and recipient. The individual who withdraws life-sustaining therapy and declares the patient dead must not participate in organ procurement and/or the transplantation of organs.²⁰ Also, the practitioner who reintubates the patient should not be involved in the medical care of the patient, the withdrawal of life-sustaining therapy, and/or the declaration of death.²⁰

Australia's DCD protocol addresses the respect of the end-of-life care of the patient and the respect of the family's

wishes. The potential donor is administered medication to relieve pain and suffering without the intent to hasten death.²⁰ Also, after the declaration of death, if the family requests longer time with the deceased, organ procurement will be delayed to respect the family's wishes.²⁰

Israel

In Israel, the law does not allow controlled DCD yet does allow uncontrolled DCD.²¹ Controlled DCD is not allowed under Israeli law (Dying Patient Act of 2005) because the withdrawal of continuous care including continuous mechanical ventilation is not allowed.²¹

With uncontrolled DCD, the health care team roles are delineated.²² The treating physician declares the patient's death.²² The coordinator of transplantation in the local hospital is then contacted.²² If the patient is an eligible donor and meets the criteria, then a dedicated uncontrolled DCD health care team assumes care of the patient.²² This uncontrolled DCD health care team is overseen by an intensive care unit physician and also includes a physician who performs arterial and venous access procedures, as well as a team that manages the extracorporeal membrane oxygenator to maintain organ perfusion.²²

In terms of informed consent, consent is required from a family member for the procurement of organs and the transplantation of organs.²² Also, it is obligatory to obtain informed consent (implied from the potential donor signing an organ donor card or obtained from a surrogate decision-maker) for the placement of cannulae for the preservation of organs.²²

China

Although DDNC is a criteria utilized for organ donation in many countries, in China, DDNC is not accepted as many members of society have not completely accepted the definition of brain death and laws addressing brain death have not been approved in China.²³ Thus, in China, a donor who is declared dead by neurological criteria must undergo controlled DCD before organ donation.²³ Only after the family decides to withdraw life-sustaining therapy is organ donation and informed consent for organ donation discussed with the family.²³ In China, potential conflicts of interest for the practitioner in terms of the interests of the potential donor and potential recipient are addressed by the treating physician pronouncing the patient dead and separate health care teams performing organ donation and the transplantation of organs.²³

Canada

The potential for ethical conflicts in the roles of the "donation physician" was the nidus for the development of the ethics guide recommendations endorsed by the Canadian Medical Association.²⁴ In Canada, a donation physician is the intensive care unit physician who is an expert in organ donation.²⁴ The donation physician provides end-of-life care for patients and provides services for organ donation.²⁴ Additional responsibilities of the donation physician may include administrative duties, education, quality assurance, and advocacy for organ donation.²⁴ The principal interest of the donation physician is for the provision of end-of-life care of the patient, meeting the patient's needs

including comfort care regardless of the potential for organ donation.²⁴ The donation physician should not participate in discussions with families about potential organ donation, proceed with end-of-life care for potential donors, or declare death of the potential donor if he or she is participating in the transplantation of organs or decisions regarding the allocation of organs.²⁴ The ethics guide recommendations support a separation of roles of physicians in the organ donation and transplantation process yet states that the separation of roles may not be possible due to available resources, regional variation, etc.²⁴ The Canadian ethics guide recommendations support role disclosure of the donation physician to the families of patients and that the donation physician's potential, actual, or perceived conflict of interest be resolved in favor of providing care in the best interest of the patient.²⁴ Yet, the guidelines state that if the clinical situation or the donation physician's relationship with the patient's family has no relevance, then disclosure of the donation physician's role is not required.²⁴ If there is a conflict among health care team members regarding the donation physician's potential, actual, or perceived conflict of interest between the interest of the potential donor and recipient, the donation physician reassures the team members that the management and treatment decisions are being made in the best interest of the patient and the donation physician is encouraged to provide transparency and open discussion regarding potential conflicts of interest.²⁴ If conflict persists, the donation physician can transfer the care of the patient to another physician or obtain a second opinion. The separation of roles is essential especially if the potential donor and recipient are being cared for by the same physician. If the donation physician is the managing physician of the potential donor, the donation physician can perform the declaration of death with a second physician confirming the pronouncement of death of the potential donor if there is a concern of conflict of interest.²⁴ A third-party opinion may be consulted if health care team members express concerns of conflict of interest.²⁴ An independent ombudsman can also be sought to address conflicts and complaints.²⁴

Consent for organ donation is confirmed by the potential donor being registered in a national registry or communication in writing of the potential donor's wishes to be an organ donor.²⁵ A potential donor is encouraged to notify family members of his or her wish to be an organ donor. If the patient's wishes are not documented, a surrogate decision-maker should base the decision for organ donation on the wishes that the patient previously expressed regarding organ donation if known.²⁵ Families who initially refuse organ donation for their family member may be approached again by the donation physician if the patient has been found to have been a registered organ donor, if there is a misunderstanding on the family's part, or there has been a provision of incorrect information by staff.²⁴ In regard to antemortem procedures, the physician discusses the purpose, potential harms, and benefits with the family and obtains informed consent.²⁴ If consent for organ donation is withdrawn, the organ donation does not proceed.²⁴

The ethics guide recommendations endorsed by the Canadian Medical Association support end-of-life care of the potential donor and that the potential donor receives analgesia to provide comfort without hastening death.²⁴ The

Dead Donor Rule is also upheld and does not allow the procurement of organs from patients who are not declared dead and prohibits killing patients for organ procurement.²⁴

Summary of Presented International DCD Programs

In summary, countries in Europe and some jurisdictions of Australia have opt-in or opt-out registration systems for organ donation, yet in Australia and in some countries in Europe informed consent is additionally obtained from the potential donor's family.^{18,20} In Israel, controlled DCD is not allowed,²¹ uncontrolled DCD is allowed,²¹ and informed consent is obtained from the potential donor's family for the procurement and transplantation of organs.²² In China, a donor who is declared dead by neurological criteria must undergo controlled DCD before organ donation and informed consent is obtained from family for the withdrawal of life-sustaining treatment and organ donation.²³ In Canada, the "donation physician" provides end-of-life care for patients and services for the donation of organs.²⁴ Yet, in Canada, the separation of roles of health care team members may not be possible with available resources or regional variation.²⁴ If there is a concern of potential, actual, or perceived conflict of interest of the donation physician in Canada, a second opinion may be obtained, a third party may be consulted, and an independent ombudsman may be contacted for advice.²⁴ In Canada, a patient's communication in writing of his or her wishes to be an organ donor or the registration of a potential donor in a national registry is confirmed for consent for organ donation.²⁵ If the patient's wishes are not documented, a surrogate decision-maker decision should base the decision for organ donation on the wishes that the patient previously expressed regarding organ donation if known.²⁵ In Europe, Australia, Israel, China, and Canada, the roles of individual health care team members are delineated to prevent a perceived, actual, or potential conflict of interest between the interests of the potential controlled DCD donor and the recipient.^{18,20,22-24}

CONCLUSIONS

The decision to donate one's organs is truly an altruistic act, saving another individual's life or improving another individual's quality of life. As the numbers of transplanted organs from DCD donors increase, it is essential to develop protocols for DCD that address the ethical issues associated with DCD. Across the world, there may be diversity in the protocols for organ DCD, yet the ethical considerations in the development of DCD protocols are essential to inform and respect donors and recipients during the altruistic and generous act of organ donation. ■■

DISCLOSURES

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