

**Non-Heart-Beating Donors:  
An Alternative to 'Brain-Dead' Donors**

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**Two Paradigms Shifts**

1. 1968, Harvard, 'brain death' (BD) i.e., heart beating donation (HBD)
2. 1993, Pittsburgh, non-heart-beating donation (NHBD) donation after controlled cardiac death, abbreviated as DCCD or DCD.
3. Common points: (i) pragmatic needs and interests of organ transplantation, (ii) implemented despite the lack of validating empirical scientific data.

**Terminologies**

NHBD – DCD – CCCD

1. 2008: the C in DCD stands for 'circulatory' instead of 'cardiac' implying that the role of the heart is secondary because it can be replaced by cardiac bypass machines.
2. Nguyen's terminology: CCCD because the cardio-circulatory system functions as one unit: the function of the heart requires circulating blood, but at the same time, without the pumping function of the heart, there would be no blood circulating.

**Uniform Determination of Death Act (UDDA)**

An individual 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*, is dead.

## Reason for CCCD

1. Pittsburgh protocol: prototype CCCD policy.
2. Reason for this new policy: “the pressing need for organs.”

The shortage of organs necessitated that the cardio-respiratory criteria be innovatively reformulated in such a way as to ensure the maximum viability of transplantable organs.

*(DeVita, 1993, Development of the University of Pittsburgh Medical Center Policy for the Care of Terminally Ill Patients Who May Become Organ Donors after Death Following the Removal of Life Support)*

## CCCD Procedure (i)

*CCCD protocol coordinates the timing of withdrawing the ventilator with the organ procurement team's readiness to procure organs*

1. The potential donor is a severely brain-injured patient but not brain dead, who is expected to die promptly (usually within about 30-60 minutes) once life support is removed;
2. Require two separate informed consents: first, the consent for the ‘do not resuscitate’ (DNR) order which permits the removal of life support, followed by the consent for organ donation;

## CCCD Procedure (ii)

3. The patient is taken to the operating room where he/she is rapidly weaned off life support. This invariably requires the administration of narcotics and sedatives to relieve or prevent discomfort;
4. As part of the ante-mortem preparation for the procurement operation, the patient is heparinized, his femoral artery cannulated, and his skin prepped and draped.

## CCCD Procedure (iii)

5. Following a *brief observation period* (the “death watch” or the “no touch” period) after onset of the cardiorespiratory arrest, the patient is declared dead.

Pittsburgh protocol: Death is declared after two minutes of (a) no pulse pressure recorded by arterial catheter, or flat EKG, (b) no heart sounds, (c) apnea, and (d) unresponsiveness.

Death watch: 2-5 minutes depending on the particular policy.

#### CCCD Procedure (iv)

6. Organ procurement proceeds immediately at the declaration of death.
7. Post-mortem procedure (Michigan protocol): veno-arterial extracorporeal membrane oxygenation (ECMO) after cardiac arrest [to] restore the flow of warm oxygenated blood during the interval between death and organ procurement.

Note: In about 25% of cases, the potential CCCD donor still lives beyond 1 hour after the removal of life support. Procurement surgery is cancelled because the ischemia during the dying process has been too prolonged, thus rendering the organs unusable.

#### Justification for CCCD (i)

1. The arguments in support of CCCD are founded upon the arguments in defense of BD. The underlying premise is:
  - a. The absolute supremacy of the brain: "*the brain is necessary for the functioning of the organism as a whole. It integrates, generates, interrelates, and controls complex bodily activities. A patient on a ventilator with a totally destroyed brain is merely a group of artificially maintained subsystems since the organism as a whole has ceased to function.*" (Bernat 1981, *On the Definition and Criterion of Death*)
  - b. Hence, "the loss of all brain functions was the unitary criterion of death."

#### Justification for CCCD (ii)

- c. "This unitary death standard could be tested in two ways: using brain-death tests if the patient's ventilation was being mechanically supported, or by showing the cessation of circulatory and respiratory functions if ventilation was not being supported."
- d. "The irreversible cessation of circulatory and respiratory functions were adequate tests of death *only* because they inevitably led to the irreversible cessation of all brain functions." (Bernat, 2006, *Are Organ Donors after Cardiac Death Really Dead?*)

#### Justification for CCCD (iii)

- e. "All death is brain death." (Antonio Battro et al., 2006, *Why the Concept of Brain Death is Valid as a Definition of Death – Pontifical Academy of Sciences*)
- f. Echoing Bernat's reasoning: "death occurs when there is permanent loss of capacity for consciousness and loss of all brainstem functions. This may result from permanent cessation of circulation and/or after catastrophic brain injury." (Shemie, 2012, *International Guidelines for the Determination of Death*, supported by the World Health Organization)

### CCCD Europe

Maastricht protocol: 'death watch' period of 10 minutes (can be tolerated by the kidneys): "in these 10 minutes of no circulation, the brain will be dead." The result would be a "situation equivalent to brain death." (Kootstra, 1996, *Ethical Questions in Non-Heart- Beating Donorship*)

### Two Pillars of CCCD

1. Patients' autonomy: consents for (i) withdrawal of life support and (ii) organ removal.
2. Presumed irreversibility: the assumption that the duration of the 'no touch' period (2-5 minutes) of asystole or circulatory arrest is sufficient to establish the irreversible loss of all cardiac-circulatory and pulmonary functions.

Note: The insistence on the exact moment of death goes against the common knowledge that it is impossible to determine the exact moment of death.

### Ethical Problems in CCCD

1. Are CCCD donors dead? This hinges on the question of irreversibility of cardiac function.
2. Use of heparin and phentolamine (potentially harmful to the donor) before the declaration of death.
3. ECMO after the declaration of death.

### Irreversibility

1. Strong sense of absolute irreversibility, which indicates that a given condition or function cannot be reversed by any technological means whether now or in the future;
2. Weak sense of relative irreversibility, which indicates that the condition cannot be reversed 'today.' Irreversibility, thus understood, is contingent on the scientific knowledge and medical technology in a particular healthcare setting. Consequently, what is thought to be irreversible today may be reversible in the future.

### Are CCCD Donors Dead? (i)

1. Does the claim of irreversible cardiorespiratory function made by CCCD protocols meet the weak sense of irreversibility, i.e., what is the time window for cardiac autoresuscitation? How long after asystole does the heart still retain the capacity to restart, and would do so if given some 'jump start' by some appropriate external stimulation.

In short: Is cardiac-circulatory function reversible after 2-5 minutes?

### Are CCCD Donors Dead? (ii)

2. "Unfortunately, no scientific studies allow a definite conclusion on how long this interval might be. Protocols and practices in the United States and other countries vary significantly in defining this interval, which reflects the *lack of scientific certainty*. [...] The shorter intervals between cessation of circulation and determination of death are problematic as to the assurance of irreversibility. *Intervals such as 2 minutes are not supported by any experimental data on the probability of auto-resuscitation and are too short to support a determination of brain death due to circulatory arrest.*" (Institute of Medicine, 1997, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*)

### Are CCCD Donors Dead? (iii)

3. "The principal conceptual problem with the Pittsburgh protocol is that it is not clear that patients are dead within a few minutes of apnea and systole. *The cessation of heartbeat and breathing must be prolonged because their absence must be of sufficient duration for the brain to become diffusely infarcted* and for the cessation of heartbeat and breathing conclusively to be irreversible. [...] The brief absence of heartbeat and breathing is highly predictive of death in this context, but [...] *at the time the organs are being procured in the Pittsburgh protocol, death has not yet occurred.*" (Bernat, 1998, *A Defense of the Whole-Brain Concept of Death*)

### Are CCCD Donors Dead? (iv)

4. According to data from resuscitation literature, cardiac function can be restored easily in persons who have been asystolic for ten to fifteen minutes in typical clinical situations.
5. Lazarus phenomenon: auto-resuscitation after failed cardiopulmonary resuscitation with times ranging from a few seconds to 33 minutes.
6. Boucek's 2008 heart transplantation from three pediatric CCCD donors (Denver's Children Hospital): (i) 1<sup>st</sup> case: 3 minutes 'no touch' period, (ii) 2<sup>nd</sup> and 3<sup>rd</sup> cases: 75 seconds 'no touch' period.

### Are CCCD Donors Dead? (v)

7. Boucek’s success clearly indicates that mechanical asystole of the donor’s heart was still fully reversible. Put bluntly, CCCD protocols allow physicians to declare cardiac death in a patient who has not suffered cardiac death.
8. “It is impossible to transplant a heart successfully after irreversible stoppage: if a heart is restarted, the person from whom it was taken cannot have been dead according to cardiac criteria. Removing organs from a patient whose heart not only can be restarted, but also has been or will be restarted in another body, is ending a life by organ removal.” (Veatch, 2008, *Donating Hearts after Cardiac Death—Reversing the Irreversible*)

### Are CCCD Donors Dead? (vi)

9. There is no firm evidence that the CCCD donor is dead, whether by neurological or circulatory-pulmonary standards, at the moment when death is declared and organ removal begins.
10. Hence, in the context of CCCD, irreversibility comes down to a decision not to intervene medically to restore circulatory and respiratory functions, in the name of respect of patient’s autonomy! Put simply, patient’s autonomy becomes the stand-in for irreversibility.

### Are CCCD Donors Dead? (vii)

Bernat’s justification of CCCD:

11. “Enacting successful public policy on issues of life and death may require *compromises on certain biological facts* [... as] they *facilitate a socially desirable goal*. [...] If DCD [donation after cardiac death] does violate the dead donor rule, it comprises a justified exception [...] because] if the DCD patient is not dead at five minutes of asystole, the patient is incipiently and unequivocally dying and will certainly be dead within minutes.” (Bernat, 2006, *Are Organ Donors after Cardiac Death Really Dead?*),
12. (i) in the name of society’s best interest, and the good of organ transplantation, scientific truths about human death can be put aside and criteria for determining death can be altered, and (ii) in the name of respect for the patient’s autonomy, this is ethically permissible.

### Slippery Slope: Who Can Be CCCD Donors?

1. Patients who are either competent with intolerable quality of life or incompetent, but not brain dead, because of severe, generally neurological, illness or injury with an extremely poor prognosis as to survival or any meaningful functional status (Institute of Medicine, 1997, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*)
2. Spike, 2000, *Controlled NHBD Protocol for a Fully Conscious Person: When Death is Intended as an End in Itself and It Has Its Own End*: a 28-year-old man with high spinal cord injury (quadriplegic and ventilator-dependent). As soon as the patient was informed of his diagnosis and prognosis, he insisted on the discontinuation of life support and donation of his organs, against the wish of his relatives. Eventually the hospital and medical team had to comply with the patient’s wish.

### ‘Pre-Mortem’ Medical Interventions

1. Heparin prevents blood clot formation in the microvasculature of organs when circulation stops, and phentolamine improves their perfusion during the patient’s dying process.
2. But, “the capacity of heparin to aggravate bleeding carries the accompanying capacity to cause a deterioration in cardiovascular performance. The use of phentolamine, a vasodilator, is certainly open to questioning since the inevitable fall in blood pressure clearly has the potential to expedite death, particularly in the established critically ill.” (Bell, 2003, *Non-Heart Beating Organ Donation: Old Procurement Strategy – New Ethical Problems*)

### Justification of ‘Pre-Mortem’ Medical Interventions (i)

DuBois’ modified principle of double effect (2001, *Non-Heart-Beating Organ Donation: Designing an Ethically Acceptable Protocol*)

1. The risks of pre-mortem use of heparin in DCD patients have been exaggerated.

NB: In a large international study, patients with ischemic stroke who received heparin subsequently suffered a hemorrhagic stroke.

2. The intent is to ensure organ viability and its function in transplant recipients.
3. The risk of hemorrhaging in donors was merely foreseen but unintended.

### Justification of ‘Pre-Mortem’ Medical Interventions (ii)

4. Since *the patient has withdrawn life support and is in the process of dying*, the good at stake is proportionate to any risk.

NB: this argument appeals to patients’ autonomy, implying that the consent for organ donation functions also as permission for whatever procedure and medication will be used for the sake of the donation.

### ‘Post-Mortem’ Medical Interventions

1. If the lungs are to be harvested, re-intubation to re-establish artificial ventilation.
2. At first, CCCD protocols employed rapid infusion of cold preservation solution into the donor’s circulatory system with the aim of initiating organ protection and preservation through cooling of organs.
3. Now: ECMO introduced by the University of Michigan in 2000.

## ECMO (i)

1. The same procedure has also been applied to patients with cardiac arrest, especially those unresponsive to conventional cardiopulmonary resuscitation, to yield better survival rates and better neurological recovery (minimal or no neurological sequelae).

## ECMO (ii)

2. If extracorporeal membrane oxygenation can: (i) restore the heartbeat, (ii) prevent further damage to the brain or restore full neurological function, along with (iii) providing adequate perfusion to the rest of the donor’s body, it would retroactively negate the death declaration made a few minutes earlier. The Michigan protocol circumvents this problem by using a thoracic aortic balloon introduced into the descending aorta and positioned above the diaphragm to block reperfusion to the heart and brain.

## Michigan ECMO in CCCD

The balloon-catheter is inserted before the declaration of death. The balloon is then inflated immediately after the declaration of death, followed by perfusion via ECMO. Confirmation that there is no blood flow rostral to the balloon is “established visually by the presence of cyanosis in the upper torso, upper extremities, and head and by the absence of carotid or radial pulses.” (Magliocca et al., 2005, *Extracorporeal Support for Organ Donation after Cardiac Death Effectively Expands the Donor Pool*)

## ECMO in CCCD for Heart Transplant

In institutions which consider doing heart transplants from CCCD donors, reperfusion to the brain can be blocked by placing a large clamp across the aortic arch prior to reperfusion of the heart and other organs.

### Ethical Issues with ECMO (i)

The use of ECMO brings back into focus the question: 'are CCCD donors dead?'

- a. If they are, there should be no need for the occluding balloon.
- b. That the occluding balloon is used necessarily implies that ECMO may reverse the cessation of respiratory/circulatory function and progression to 'brain death.' This in turn means that CCCD donors are not dead.

### Ethical Issues with ECMO (ii)

- c. Hence, by depriving oxygenated blood to the heart and brain by means of an inflated thoracic aortic balloon to block reperfusion above the diaphragm would of itself constitute an actual cause of death.

It is here that organ transplantation, in its insatiable quest for fresh and viable organs, fully reveals its inner darker side.

### Conclusion

1. CCCD closely borders euthanasia because in the last analysis, the only justification for its practice is the principle of respect for autonomy: the autonomy in giving consent to a DNR and a consent to donate organs.

NB: it is not a DNR in which the patient is let to progress to natural death, however.

2. CCCD is a veiled form of euthanasia; it is the immediate precursor of the overt practice of organ donation after euthanasia, now established in Belgium and the Netherlands.