

## **6. Defining Death in Donation after Circulatory Determination of Death**

### Medical Controversies

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### **1. Introduction**

Over the past 50 years, the concept and the determination of death have been given increasing attention in the scientific literature. Death determination was not the prerogative of physicians until the 18<sup>th</sup> century, before which its determination was the responsibility of families or undertakers (Powner 1996). Mainly due to the fear of being buried alive and, later, due to the development of resuscitative technology, medicine has become the field of expertise for the determination of death. Beginning in the 18<sup>th</sup> and 19<sup>th</sup> centuries, death was determined by physicians based on the cessation of functions of the three vital organs: the heart, the lungs, and the brain. At that time, because the functions of these three vital organs were interdependent, death was a unitary phenomenon. When one vital organ ceased to function, the other two rapidly ceased to function as a result. The concept of death determination itself was straightforward and barely discussed in medical writings.

The development of mechanical ventilation in first half of the 20<sup>th</sup> century forever changed this paradigm (Rodríguez-Arias 2017). Advances in medical technologies now permitted physicians to sustain the functions of the heart and lungs despite the cessation of brain function resulting from severe brain damage. Medical technologies thus created a new human state, one in which the interdependency of functions among the three vital organs was lost. This new human state initiated the first serious discussions on the concept of death within the medical profession.

Since the 1960s, death determination has been conceptualized as either the cessation of functions of the whole brain (Mollaret 1959; Beecher 1968) or of circulatory and respiratory functions (President's Commission 1981). Throughout this time, as scholars have debated whether brain death was a coherent concept of death (Veatch 1993; Bernat 1981; Giacomini 1997), the acceptance of brain death as a criterion for death has grown worldwide (Capron 2001). The determination of brain death is now accepted by the international medical profession (Wijdicks 2010). When a patient is determined dead based on the brain criterion of death, his respiratory and circulatory functions are maintained by artificial means, such as the use of mechanical ventilation. Brain

tests are used to prove the absence of any brain functions, particularly the absence of consciousness, brain stem functions, and spontaneous respiration.

Donation after circulatory determination of death (DCDD) programs were developed in the 1980s in order to address the scarcity of organs; they have since been developed in many countries around the world to increase the organ pool for transplantation. However, DCDD programs also challenge the concept and determination of death, and certain countries have chosen not to develop such programs, for moral, cultural, historical and also legal reasons. For example, DCDD remains illegal in Germany, possibly because of historical sensitivity around euthanasia.

The United States, Canada, the United Kingdom, and the Netherlands, among other countries, have mainly developed controlled DCDD programs (Magliocca 2005; Bos 2005; Summers 2015; Shemie 2006). Here, organ donation occurs after the cessation of the donor's circulation, following the withdrawal of life-sustaining therapies. The decision to withdraw life-sustaining therapies is made independently of the question of organ donation (Dalle Ave 2017a); it is made when the patient or family no longer desire the prolongation of life, and when doctors judge further medical treatment to be inappropriate or futile (Bosslet 2015).

France and Spain have pioneered the development of programs of uncontrolled DCDD (Burnod 2007; Antoine 2007; Mateos-Rodriguez 2010; Mateos-Rodriguez 2012). This system applies in cases of unexpected sudden cardiac arrest. Once it has been established that resuscitative efforts are futile, the patient is transferred to an uncontrolled DCDD medical center. Donation occurs once death has been determined at the hospital.

In DCDD programs (controlled and uncontrolled), death occurs after a cardiac arrest, which leads to the cessation of the circulatory and respiratory functions. Death is determined after a purposely short period of cardiac arrest and circulatory cessation, usually five minutes, to allow a sufficient quality of organs suitable for transplantation. The way death is determined in DCDD varies among countries.

In this chapter, we focus on the ethical issues raised by the determination of death in DCDD. Our purpose is to offer a conceptual justification for death determination in this context and to highlight practical pitfalls, but not to offer a normative analysis of the concept of death in general. We first describe and analyze the determination of death in DCDD by discussing the concepts of irreversible and permanent cessation of functions. Second, we discuss the issues raised by the use of extracorporeal membrane oxygenation (ECMO) in DCDD. Third, we analyze the unique issues raised by heart DCDD, and fourth, the issues raised by uncontrolled DCDD. Finally, we propose a new way to determine death in DCDD: the brain circulation determination of death.

## 2. Description and Analysis of the Determination of Death in DCDD

In both uncontrolled and controlled DCDD programs, death is determined after a short stand-off (no-touch) period, defined as the time between complete circulatory cessation and the determination of death. Although the stand-off period varies among countries, five minutes has become the norm. A short stand-off period is desirable to minimize the warm ischemia time and thereby optimize graft outcome.

The criteria to determine death vary among countries. In the US and many other countries, death is determined by fulfilling one of two criteria: the irreversible cessation of circulatory and respiratory functions, or the irreversible cessation of all functions of the entire brain, including the brain stem (Uniform Determination of Death Act 1997).

Laws and codes of practice in other countries, including France, Canada (The Law Reform commission of Canada 1970), the United Kingdom (Academy of Medical Royal Colleges 2008), and Switzerland (Swiss Federal Act 2004), unify death determination under a single brain criterion. In Switzerland, for instance, “a person is dead when all cerebral functions, including the brain stem, have irreversibly ceased” (Swiss Federal Act 2004).

Several critics have argued, however, that DCDD donors are not dead at the time of the determination of death (Rady 2013; Joffe 2011; Potts 2007; Marquis 2010; Miller 2008). Death is, by definition, an irreversible state, and after only five minutes of circulatory cessation, the cessation of respiratory and circulatory functions might be potentially reversible. Thus, the five-minute stand-off period is obviously not sufficient to achieve the irreversible cessation of circulatory, respiratory, or brain functions. Several studies, unrelated to DCDD protocols, showed good neurological outcomes for some patients who suffered an out-of-hospital cardiac arrest with a no-flow period of 20 to 30 minutes (Hara 2015).<sup>1</sup> These studies reveal a fact known widely by physicians: after only five minutes of cardiac arrest, it may be possible to medically restore circulatory, respiratory and some brain functions. Furthermore, the use of advance resuscitative technique, such as extra-corporeal membrane oxygenation (ECMO), may also restore circulation after intractable cardiac arrest (Megarbane 2011). Additionally, animal studies have demonstrated evidence that circulatory, respiratory and some brain functions could be restored after cardio-circulatory cessation for as long as 30–60 minutes (Hossmann 1987; Hossmann 1973). Thus, it is clear that circulatory function may be restorable, even after a cessation of five minutes.

These facts have led some critics to conclude that DCDD protocols breach the dead donor rule, an ethical and legal guideline that requires that “donors must not be killed in order to obtain their organs” and that “organ retrieval cannot cause death” (Robertson 1999: 6).

One of us (James Bernat) has addressed the question of whether DCDD programs breached the dead donor rule by highlighting the distinction between the irreversible and permanent cessation of circulatory and respiratory functions. Bernat states that: “whereas, irreversibility is a requirement for the definition and criterion of death, [...] a circulatory-respiratory death determination requires demonstrating only that circulatory and respiratory functions have ceased permanently” (2010: 249).

Thus, an individual who has permanently lost his circulatory and respiratory functions is determined dead and the dead donor rule is not breached.

Bernat further points out that a function is said to be irreversibly lost when no available intervention or technology can restore that function. Irreversibility is thus an unequivocal state, which implies a technical impossibility, independent of our intention or action (Bernat 2006). By contrast, a function is said to be permanently lost when that function cannot restart spontaneously (autoresuscitation) and will not

<sup>1</sup> No-flow is the time interval between collapse and the initiation of cardiopulmonary resuscitation.

be restored by medical intervention. Permanent cessation is thus an equivocal state, which implies a technical possibility, and one that is dependent on our intention and action (*ibid.*). After a cardiac arrest, a patient will have the permanent cessation of circulation after five minutes of observation, and this state will become irreversible with time if no actions to restore circulation are performed.

In practice, physicians typically determine death (particularly in the acute setting) once the cessation of respiratory and circulatory functions is permanent. For instance, in the intensive care unit after withdrawal of life-sustaining therapies, cardiac and respiratory functions progressively decrease until they cease completely. Once the heartbeat has stopped, physicians may determine death within as little as a few minutes.

To confirm permanent cessation, the physician must ensure that the period during which auto-resuscitation could occur has elapsed. From the point of death determination, the patient will evolve from a permanent to an irreversible cessation of circulation and respiration. Because no action will interfere with this process, permanency is a valid surrogate on which to base the determination of death, and in practice there is no need to wait longer.

Bernat argues that death could be determined in DCDD protocols based on the permanent cessation of respiratory and circulatory functions if two conditions are satisfied. First, spontaneous resumption of ceased functions (auto-resuscitation) cannot occur; and second, medical interventions will not be attempted to restart the ceased functions (Bernat 2010).

These necessary conditions in DCDD protocols raise two issues. First, how long must a physician wait to ensure the impossibility of auto-resuscitation? Second, how do resuscitative techniques (such as ECMO, Cardiopulmonary resuscitation (CPR), and mechanical ventilation) that are instituted after the determination of death interfere with the determination of death? Ethically, these questions are extremely important: if the patient is not truly dead when organs are retrieved, the dead donor rule would be breached and organ removal by physicians could actually cause death. This would be a grave violation of professional duties and the principle of non-maleficence.

To answer the first question regarding waiting time, we can cite studies that assess how many minutes of circulatory cessation confidently exclude the possibility of auto-resuscitation (Hornby 2010). Importantly, the answer differs between controlled and uncontrolled DCDD protocols. In controlled DCDD, no patients have demonstrated auto-resuscitation after one minute of circulatory cessation, whereas in uncontrolled DCDD after a primary cardiac arrest, no patients demonstrated auto-resuscitation after seven minutes of circulatory cessation. Because the number of patients studied has been relatively small, more studies are necessary to determine more accurately exactly how long it is necessary to wait after circulatory cessation to ensure the impossibility of auto-resuscitation, and thus to permit DCDD programs to determine an appropriate stand-off period. At present, it appears that a five-minute stand-off period in controlled DCDD is long enough to exclude the possibility of auto-resuscitation, but this is not long enough to confidently exclude the possibility of auto-resuscitation in uncontrolled DCDD, which requires ten minutes.

In the next two sections we address the second question: how the use of resuscitative techniques after the determination of death can interfere with the determination of death. We analyze the use of ECMO in DCDD and the unique case of DCDD heart transplantation.

### 3. The Use of ECMO in DCDD

An ethical imperative of organ donation is to procure organs in good condition. Some controlled DCDD protocols use ECMO to resume bodily circulation following the determination of death, only to benefit the organs' condition (Magliocca 2005; Farney 2011; Lee 2005; Rojas-Pena 2014, Oniscu 2014). After a stand-off period, ECMO is initiated to decrease warm ischemia time before organ procurement begins.<sup>2</sup> ECMO can improve future graft outcome by maintaining organ perfusion until procurement. Some uncontrolled DCDD protocols in France and Spain (Burnod 2007; Mateos-Rodriguez 2010) also use ECMO as a method of organ preservation, after death has been determined.

The use of ECMO may be ethically justified from a utilitarian perspective because it may improve the organs that are donated. However, it raises ethical issues such as (temporarily) reversing the determination of death and thus potentially harming the patient. If it is used during a state of permanent cessation, before the cessation becomes irreversible, ECMO could restore brain, heart and circulatory functions. This situation creates a risk of harm to the donor. To avoid such risk, a supra-diaphragmatic aortic occlusion balloon is usually inserted to block ECMO blood flow to the brain and thorax and thereby to prevent the restoration of brain and heart circulation.

The risk of restoring brain and heart functions is not a fantasy or theoretical risk and was acknowledged in the initial controlled DCDD protocols using ECMO. In these protocols, instead of inserting an aortic occlusion balloon, intravenous lidocaine was administered to prevent the restoration of heartbeat, and/or phenobarbital was administered to prevent the restoration of brain functions. What effect on death determination would ECMO produce if circulation was resumed after death was determined? Even if upper body circulation was prevented through the use of the aortic occlusion balloon, lower body circulation would be resumed through the use of ECMO. Technology again forces us to reconsider our criteria for death, and whether they remain ethically appropriate. Is the patient dead under those conditions? The answer depends on which criterion of death one uses. If one determines death based on the circulatory criterion, it may be difficult to say whether the patient is dead or alive: above the aortic balloon there is no circulation, but below the aortic balloon circulation remains. Here, the brain criterion is more applicable, by which the donor is dead when his brain functions have ceased irreversibly, irrespective of what happens to his bodily circulation. In DCDD that means that brain death could occur under the condition that brain circulation is confidently prevented, even if bodily circulation persists. If brain circulation stops, brain function will cease, initially permanently, and then irreversibly. Later we discuss in greater detail the implication of the use of a brain criterion of death in DCDD.

Now, let us focus on the fact that to prevent harm, brain circulation must be confidently prevented despite the use of ECMO. Note that the balloon does not cause brain death; it prevents the brain being reoxygenated, which physicians must accomplish to maintain the pre-existing determination of death. But can one be certain that the aor-

<sup>2</sup> The warm ischemia time is the interval between the moment donors develop severe ischemia (often at a systolic blood pressure threshold of 80 mmHg or from cardiac arrest) and the initiation of organ perfusion.

tic occlusion balloon is not misplaced when ECMO is started, or will not be displaced or malfunction during the use of ECMO? In the case of aortic occlusion balloon malfunction or displacement, because the brain tissue is sensitive to reperfusion for 30–60 minutes, there is a risk of restoring brain circulation, reviving the patient, and thus harming the donor. This risk is not theoretical; we have described such cases (Dalle Ave 2016a). We believe, as do others (Manara 2012), that no intervention should be used that may potentially restore brain functions after the determination of death (Dalle Ave 2016a; Bernat 2008).

#### 4. Heart DCDD

There are only a few heart DCDD programs currently operating around the world, probably because of the sensitivity of the heart to warm ischemia time and related technical difficulties. The first heart DCDD was performed in 1967 by Barnard in Cape Town (Barnard 1967). In 2008, Boucek et al. published three cases of heart DCDD transplanted in neonates (Bouceck 2008). The stand-off period of this Denver DCDD protocol had been reduced from three minutes to 75 seconds, leading critics to question whether the neonatal heart donors were truly dead at the time of organ procurement. It is only since 2015 that heart DCDD programs have been developed elsewhere, principally in the United Kingdom (Ali 2009; Walsh 2015; Smail 2018; Messer 2017) and Australia (Dhital 2015; Chew 2019).

One of the two heart DCDD protocols of the United Kingdom is creative (Ali 2009; Walsh 2015). As in any controlled DCDD protocol, after withdrawal of life-sustaining therapies, circulatory cessation is followed by the determination of death. After a five-minute stand-off period, a thoracotomy is rapidly performed to clamp the aortic arch vessels and to insert ECMO catheters to resume bodily circulation. Instead of the aortic occlusion balloon, which excludes heart circulation, the UK heart DCDD protocol uses an aortic arch clamp. This heart DCDD protocol permits the resumption of full bodily circulation, including that of the heart, while excluding brain circulation. Once ECMO has resumed circulation, the UK heart DCDD protocol waits until the heart resumes normal function, after which ECMO is weaned. If the heart continues to demonstrate good function, it is deemed suitable for transplantation and is thus procured. The UK heart DCDD protocol thus essentially converts a DCDD organ donor into a brain-dead donor.

Like all DCDD protocols using ECMO, the UK heart DCDD protocol raises the issue of whether it retroactively interferes with the previous determination of death. Does the use of an aortic clamp confidently prevent the restoration of brain circulation during the use of ECMO? If not, the donor may incur harm. An aortic clamp may block blood circulation through the carotid and vertebral arteries, but it may “spare small collateral arteries from the segmental spinal arteries that arise from the thoracic aorta and anastomose the branches of the vertebral arteries. These collaterals conceivably could provide a small degree of perfusion to the brainstem” (Dalle Ave 2016b: 315).

Bedside assessment may provide some clues that the brain retains some brain perfusion with the use of ECMO. For instance, clinical signs of transtentorial brain herniation – such as sudden severe hypertension and bradycardia, followed by a rapid hypotension – after the determination of death and during the use of ECMO, may

constitute evidence that the last brain functions are ceasing at that precise moment. This finding would imply that the brain had preserved some brain functions before the occurrence of this Cushing reflex, and thus that the donor was not dead, probably because ECMO permitted the preservation of a small degree of brain perfusion.

As we have explained elsewhere, to ensure that the aortic arch clamp completely blocks brain perfusion, brain circulation should be tested and proven absent. In particular, brain stem perfusion should be proven to have stopped because it can continue to function with a smaller blood flow than the cerebral hemispheres (Dalle Ave 2016b: 315).

The Australian heart DCDD protocol differs from that of the UK by not using ECMO (Dhital 2015; Chew 2019). In their protocol, a stand-off period of two or five minutes is used. To better preserve the future graft function, a “normothermic *ex vivo* cardiac perfusion device” is used to decrease the cold ischemia time, namely, the time from heart procurement to heart transplantation (Burnod 2007).

Controlled DCDD using a stand-off period as brief as two minutes (Boucek 2008; Dhital 2015) raises issues regarding the concept of permanent cessation. After circulatory cessation, the permanent cessation of circulation occurs once the possibility of auto-resuscitation has elapsed. A stand-off period as short as two minutes may put the donor at risk of auto-resuscitation, potentially breaching the DDR. That is why, until further studies of controlled DCDD programs have determined with greater accuracy the exact minimum duration of circulatory cessation that excludes the possibility of auto-resuscitation, we support a secure stand-off period of five minutes.

In addition to the previously described protocol using ECMO, the UK has developed a heart DCDD protocol similar to Australia’s (Smail 2018; Messer 2017). After the stand-off period of five minutes, the heart is rapidly procured and reperfused in an *ex situ* normothermic platform using the Organ Care System. In this protocol, the donor’s abdominal organs are perfused by the use of ECMO, but not the heart because the descending aorta is clamped.

## 5. Uncontrolled DCDD

Uncontrolled DCDD programs raise several ethical issues. We focus here on those related to the determination of death. Uncontrolled DCDD programs (Burnod 2007; Mateos-Rodriguez 2010) concern donation after a sudden cardiac arrest, usually in an out-of-hospital setting. Once physicians deem them to be futile, resuscitations efforts are stopped. At that point, if the patient is suitable for an uncontrolled DCDD protocol, CPR efforts are resumed, and the patient is transferred to the uncontrolled DCDD medical center. The goal of CPR efforts at this stage is not to save the patient’s life, which is no longer possible, but to preserve organ perfusion to ensure better future graft outcome. At the uncontrolled DCDD center, death is determined, followed by the initiation of ECMO or cold perfusion to preserve the organs for future transplantation. Organ procurement proceeds once consent to organ donation has been obtained. Four unresolved medical-ethical issues remain in the determination of death in uncontrolled DCDD programs, which we describe in the following.

## 5.1 The Use of CPR Once the Patient has been Considered Unsalvageable

As stated, when physicians judge that further resuscitation efforts are futile, CPR is stopped and the patient is considered to be dead (even though in some protocols, death is formally determined later at the hospital). The only justification for accepting the patient into an uncontrolled DCDD protocol – a decision that is made immediately after CPR has been stopped – is that the patient is unsalvageable and presumed dead. When CPR is resumed to preserve the organs, and despite no intent to save the patient's life, CPR produces a risk of restoring bodily circulation sufficient to restore brain circulation and thus brain function. This situation can harm the patient by temporarily returning him to life that will confer no benefit.

## 5.2 The Use of ECMO after the Determination of Death

The same considerations discussed in section III are relevant here. After the determination of death, no measure that could restore brain circulation and function should be used because it could revive the patient.

## 5.3 The Conflict of Interest between Uncontrolled DCDD Programs and ECMO-Assisted CPR (E-CPR)

E-CPR is a resuscitation technique using ECMO when conventional CPR cannot restore a patient's life (Stub 2015; Sakamoto 2014). There is evidence that advances in E-CPR may improve the outcome of patients suffering from an unexpected refractory cardiac arrest. E-CPR protocols and uncontrolled DCDD protocols are similar (Dalle Ave 2016c). The vexing question facing the resuscitative team is: given a patient with a refractory cardiac arrest, how should they decide between entering this patient into an E-CPR protocol to attempt to save his life, or into an uncontrolled DCDD protocol to convert him to an organ donor and save the life of a potential organ recipient? In some situations, there may be no hospital nearby that could save the patient's life, but there may be hospitals nearby with suitable organ donation programs (Dalle Ave 2016c). Attempting to save the patient's life with E-CPR may well be futile and might be judged inappropriate even if organ donation was not a possibility. The inherent conflict of interest has a major impact on the determination of death. If instead of attempting resuscitation by an E-CPR protocol, the patient was prematurely entered into an uncontrolled DCDD protocol, he would be declared dead, even though he might have been saved by a resuscitative technique.

To avoid a 'third world resuscitation-first world donation' situation (Dalle Ave 2016c), saving patients' lives in case of cardiac arrest should remain the highest priority. Countries should primarily focus on the development of resuscitation techniques, such as E-CPR, and donation should be considered only secondarily. One solution to avoid such a conflict of interest would be to have uncontrolled DCDD programs only in centers that use E-CPR. If E-CPR is not an option, and if no other lifesaving options are available, termination of resuscitation efforts could be considered. Only after the final step should death be determined following an adequate stand-off period, at which time organ procurement may be pursued.

## 5.4 The Optimal Duration of the Stand-Off Period

Usually, the stand-off period used in uncontrolled DCDD programs is five minutes. However, one survey showed that, in the context of an unexpected cardiac arrest, auto-resuscitation to restored circulation is possible for up to seven minutes (Hornby 2010). To ensure that a state of permanent cessation of circulation exists, death should be declared only after a stand-off period of at least ten minutes in the context of uncontrolled DCDD.

## 6. The Brain Circulation Determination of Death

In DCDD, the permanent cessation of circulation as a criterion of death can be retroactively negated using resuscitative technologies such as ECMO. Previously, we suggested that the permanent cessation of brain circulation is the essential underlying determinant of death in the context of DCDD. We therefore suggested a new acronym in place of DCDD: DBCDD – *organ donation after brain circulation determination of death* (Dalle Ave 2017b). We now analyze the role of the permanent cessation of brain circulation in determining death in DCDD.

After circulatory cessation, ischemia develops progressively in different organs. Because the brain is the organ most sensitive to ischemia, it is affected first and heart ischemia follows. After circulatory cessation, brain functions cease within minutes, first permanently, and after 30–60 minutes, irreversibly. If one accepts brain death as a valid criterion of death, one may apply this same criterion in the DCDD context. The concept of brain death holds that patients whose brain functions have ceased irreversibly, but who have their circulation sustained artificially, are considered dead (see also chapter 5 in this book). In the discussion that follows, we assume that the irreversible cessation of brain functions is a theoretically valid criterion of death. However, we will show that it is not how death is usually determined in practice, and it may also not be the best way to determine death at the bedside, including in DCDD programs.

If DCDD programs employed the standard brain death criterion to determine death, they would become impossible. Because proving the irreversible cessation of all brain functions would require at least 30–60 minutes of circulatory cessation, most organs would be unsuitable for transplantation.

Another option would be to require only the permanent cessation of all brain functions to determine death. This step would be a departure from the usual understanding of the brain death criterion, which requires irreversibility. The justification to switch from the irreversible to the permanent cessation of all brain functions is the same as the justification used to switch from the irreversible to the permanent cessation of circulatory functions. In practice, physicians often determine death during a state of permanent cessation, whether the functions which are permanently lost are those of the heart, the circulation, or the brain. Thus, in DCDD, one could use the same standard to determine death, ensuring the two conditions proposed by James Bernat, i.e. that brain circulation must not be restored after death, and there can no longer be a possibility of auto-resuscitation.

An additional necessary condition is that the permanent cessation of all brain functions must be complete. It is necessary to wait long enough after circulatory cessation

that all brain functions have ceased. Death should never be determined (or organs procured) while the patient retains brain functions because it could create the potential of awareness and suffering. Only a few minutes of circulatory cessation are necessary to assure that all brain functions have ceased permanently. A stand-off period of five minutes would ensure that the possibility of auto-resuscitation has elapsed and that all brain functions are permanently lost.

The requirement that brain circulation not be restored after the determination of death demands that any technologies that could restore bodily circulation must be omitted after the determination of death. These technologies include ECMO, CPR, and even lung inflation, all of which may stimulate the heart to restart functioning and restore circulation. If those techniques are used after the determination of death, brain circulation must be excluded, and the absence of brain circulation proven with certainty. This requirement may be a challenge to achieve in practice.

To use the brain circulation criterion of death to determine death in DCDD, one should determine which tests will be used to confirm death. We argue that because circulatory cessation irremediably leads to the cessation of brain function, the confirmation of the cessation of systemic circulation is sufficient to confirm death. This can be done using an echocardiography, proving no opening of the aortic valve, or of an electrocardiogram, proving the absence of electrical cardiac activity. The use of specific brain death tests is unnecessary, despite claims to the contrary (Swiss Academy of Medical Sciences 2019).

The proposal of basing the determination of death in DCDD on the brain circulation criterion has the advantage of unifying death under a single criterion. Elsewhere, we have explained the proposal of proving the absence of brain circulation in the context of organ donation after brain death (DBD) (Dalle Ave 2018). There is evidence that some patients determined dead by the brain death criterion – i.e. patients who have no apparent brain functions but who have their circulation artificially sustained – may retain some brain functions despite having been declared dead. To reduce the inconsistency between the brain death criterion and the tests for brain death, we proposed the requirement of showing the absence of brain circulation by a validated neuroimaging test. We argue that showing absence of brain circulation could be a unique criterion to determine death in both DCDD and in DBD. Because currently no method completely excludes brain circulation, further research is necessary before this idea can be implemented.

## 7. Conclusion and Future Perspectives

The controversy over whether the DCDD donor is dead after five minutes of complete circulatory cessation can be resolved by accepting the medical practice standard for death determination as the permanent cessation of circulation and respiration. Even though many death statutes employ the term ‘irreversible cessation’ of circulation and respiration, and the biological concept of death requires irreversibility, the medical practice standard for death determination has always been their permanent cessation (Bernat 2013). There is no compelling reason why death determination in the context of organ donation should require a change in medical practice from the standard that physicians widely use to declare death in non-donation circumstances.

All existing DCDD programs implicitly accept permanent cessation as death by requiring only two to five minutes of circulatory and respiratory cessation before death is declared, despite knowing that the loss of these functions may not be irreversible at that point. Only a few groups have explicitly accepted the permanent vs. irreversible distinction (American Academy of Pediatrics Committee on Bioethics 2013), but there is no justification for hospitals to sponsor DCDD programs other than endorsing this conceptual distinction. We are simply making the concept underlying prevailing DCDD practices explicit. Clear definitions of the underlying concepts of DCDD are essential for ethical decision-making, because without them patients might be harmed by unnecessary interventions, or organs removed when patients are not really dead. Clarity is also essential for transparency and trust.

For physicians to accurately declare death on the basis of permanent cessation of circulation and respiration, there must be no subsequent interventions that restore circulation because the cessation would then no longer be permanent. If cessation is not permanent, organ removal could in some cases constitute killing the patient. That is why there must be a complete proscription against the use of CPR, ECMO, and all other resuscitative technologies that restore or partially restore brain circulation. There also must be a reliable method to determine that circulatory cessation is complete, such as showing zero forward blood flow by an arterial catheter or Doppler, or by an echocardiogram showing no opening of the aortic valve. The third condition is that the no-touch interval after circulatory cessation must be of sufficient duration to exclude the possibility of auto-resuscitation. Auto-resuscitation to restoration of circulation is extremely unlikely after one minute in the controlled DCDD patient but may occur up to seven minutes after circulatory cessation in cases of uncontrolled DCDD because of the prior resuscitative treatments.

We believe that for their future success, all DCDD programs should use the determination of death that requires showing only the permanent cessation of brain circulation. Fulfilling this criterion also requires that any resuscitative efforts including ECMO and chest compressions must not restore any circulation to the brain. Ultimately, both circulatory and brain criteria of death depend on the permanent and total absence of brain circulation.

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