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# Does Controlled Donation after Circulatory Death Violate the Dead Donor Rule?

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#### ABSTRACT

The vital status of patients who are a part of controlled donation after circulatory death (cDCD) is widely debated in bioethical literature. Opponents to currently applied cDCD protocols argue that they violate the dead donor rule, while proponents of the protocols advocate compatibility. In this article, we argue that both parties often misinterpret the moral implications of the dead donor rule. The rule as such does not require an assessment of a donor's vital status, we contend, but rather an assessment of whether procurement of organs in cDCD *cause* the death of the donor or not. We then argue that commonly practiced cDCD protocols do not violate the dead donor rule, since the donation does not trigger or cause the death of the donors.

#### **KEYWORDS**

Organ donation; organ transplantation; death; dead donor rule; controlled donation after circulatory death; ethics

# INTRODUCTION

Since the 1960s, the practice of organ donation has been governed by an axiomatic adherence to the dead donor rule. The dead donor rule is often believed to require that donors must be dead before organs can be procured, but this is not so clear according to the most generally acknowledged definition of the rule. It merely requires that procurement of organs should not cause the patient's death. This misunderstanding has provoked a major controversy in bioethical literature and medical practice about whether controlled donation after circulatory death (cDCD) respects the rule. However, we will argue that some of the key arguments in this debate do not follow from the dead donor rule, but rather from a discussion of death criteria that are strictly speaking not affected by the dead donor rule.

The use of cDCD has increased substantially in the last two decades, and in Europe, several countries such as the U.K., France, Spain, and many others have employed the practice (Lomero et al. 2020). The ambition behind introducing cDCD, as a supplement to the current practice of donation after brain death (DBD), is to reduce the ever-increasing waiting lists for new organs, waiting lists that by far exceed the organs available (Council of Europe n.d.). Even though a report from the U.K. has shown a dramatic increase in the number of deceased organ donors, primarily due to cDCD (Johnson et al. 2014), the practice remains an area of disagreement.

As an example, cDCD is forbidden by professional medical rules in Germany (den Hartogh 2019). In Norway, a preliminary cDCD protocol was temporarily suspended in 2017, due to disputes among health professionals (Lomero et al. 2020). Physicians from different Norwegian hospitals were unable to agree on when patients should be considered dead, and how death should be correctly diagnosed in cDCD protocols.<sup>1</sup> Similarly, in bioethical literature, some scholars suggest that current cDCD protocols violate the dead donor rule (Marquis 2010; Miller and Truog 2012), while others advocate compatibility (Bernat 2010; Ave, Sulmasy, and Bernat 2020; Lizza 2020; Rodríguez-Arias, Smith, and Lazar 2011).

In this article, we will discuss whether the dead donor rule is violated under the standard cDCD protocols that are followed in most European countries. We will argue that to some extent the debate about cDCD is misplaced by mainly focusing on whether the

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<sup>&</sup>lt;sup>1</sup>For a brief overview of the Norwegian debate in which different physicians express their view, see the coverage from the Norwegian news site NRK (Thunold 2019).

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donor is dead at the time organs are procured, since this is not the key issue addressed by the dead donor rule. It should be noted that we will focus on cDCD protocols where abdominal organs are removed. This is because cDCD of the heart and lungs is only practiced in a few countries (Parent et al. 2020), and because this practice could raise distinct concerns regarding the dead donor rule that exceeds the scope of this article. Thus, when we use the term organs on the following pages, we will be referring to the abdominal organs.

The article will proceed as follows: In Section "The Dead Donor Rule," we provide a description of the dead donor rule and show that its implications are sometimes mistaken. In Section "The Current Bioethical Debate," we give a brief overview of the current debate about cDCD to show why and to what extent it is based on a mistaken assumption about the content of the dead donor rule. In Section "The Dead Donor Rule and CDCD," we present our argument as to why we think that cDCD is compatible with the dead donor rule. Before we conclude, we will, in Section "The Dead Donor Rule and Normothermic Regional Perfusion," discuss whether our argument is compelling in cDCD protocols where organ preservation techniques are applied.

## THE DEAD DONOR RULE

The dead donor rule was first described by John Robertson in 1989, although it had been an uncodified standard, at least in the U.S., since the 1960s (Arnold and Youngner 1993). The rule is an important ethical norm in organ donation that prohibits physicians from causing the death of a patient for or by procurement of organs (Robertson 1989, 1999). The restriction that physicians should not cause the death of a patient is a specification of the deontological restriction against the intentional killing of innocent persons (Miller and Truog 2012). The restriction can be grounded in a principle of nonmaleficence or simply in the belief that killing or causing death is inherently wrong (Veatch and Guidry-Grimes 2020). Even though some are questioning whether it is always wrong to kill, exemplified by the debate about euthanasia or mercy killing, there is a general belief in medical ethics that physicians should never kill or cause the death of a patient (Veatch and Guidry-Grimes 2020). We will not engage in this discussion here but accept the current status quo in most countries and medical communities: killing or causing the death of patients should be avoided.

Some have suggested that the dead donor rule also prohibits the procurement of organs before death (Arnold and Youngner 1993); this is not the case. The core requirement—and the only one—of the dead donor rule is that donation should not cause the death of patients. This has been noted by others (Ave, Sulmasy, and Bernat 2020; Omelianchuk 2018), but is also clearly emphasized by Robertson when he writes:

The dead donor rule limits only organ retrieval that causes death. It says nothing about situations in which organ retrieval itself would not cause death. Removing nonessential organs or tissue from incompetent persons on the basis of substituted consent—for example, retrieving kidneys from retarded individuals or from those in persistent vegetative states—would not violate the dead donor rule because organ or tissue retrieval in those cases would not cause death. (Robertson 1999, 7)

This passage shows that, as Robertson describes it, the only clause in the dead donor rule is that organ procurement should not kill the patient or in any way cause the patient's death. Further, that non-lethal organ retrieval from living individuals does not violate the rule, although it might violate other ethical norms or principles. Now, it might be objected that we provide Robertson with too much authority regarding the definition of the dead donor rule, and that is possibly true. It should, however, be noted that it is common for scholarly authors to attribute the definition of the dead donor rule to Robertson (Arnold and Youngner 1993; Bernat 2013; Chaten 2014; Rodríguez-Arias 2018; Miller and Truog 2012), although their interpretation of the rule might differ.

It might seem like a logical extension of the requirement not to cause the death of donors that donors should be dead at the time of organ procurement. If death has already occurred, we are at least sure that procurement will not cause it. As noted by Adam Omelianchuk, the death requirement is the operational result of a precautionary approach to comply with the requirement that donation must not cause the death of the donor (Omelianchuk 2018). However, while requiring that donors must be dead might serve as a practical safeguard against violating the dead donor rule, it does not follow from this precautionary measure that donation is always incompatible with the rule when donors are not known to be dead.

Even though we have now established that the dead donor rule does not require that donors must be dead before organs can be procured, we will admit the paradoxicality of having an ethical rule whose content is not properly described by its name. If the rule does not require that donors be dead upon procurement of organs, then why is it referred to as "the dead donor rule?" The answer may simply be that it is assumed that the removal of vital organs like the liver or kidneys from a yet-to-be deceased donor will always cause the donor's death. As Robertson puts it: "Removal of organs necessary for life prior to demise would violate the dead donor rule regardless of the condition or consent of the donor because removal of those organs would kill the donor." (Robertson 1999, 6).

It is, however, not given that vital organs cannot be removed from patients if we were to learn that removal of these organs would not cause the patient's death. It could be argued, as we will do later, that in some cases where patients are close to being dead, the organs are no longer necessary for life, and removal of them will not cause death.

In the following section, we will give a brief overview of the debate about cDCD and the dead donor rule in the bioethical literature and show how it is widely affected by the slightly mistaken assumption that donors must be dead if we are to avoid violations of the dead donor rule.

#### THE CURRENT BIOETHICAL DEBATE

To show how the current bioethical debate is affected by the assumption that donors must be dead before organs can be procured, it is helpful to start with a brief description of cDCD. Patients enrolled in cDCD protocols often have a catastrophic brain injury to a degree where withdrawal of life support is justified on the grounds of best interest, but they do not fulfill the neurological criterion for death - the irreversible loss of all brain functions. Instead, death is determined based on a circulatory criterion, the irreversible loss of circulatory and respiratory functions, following the withdrawal of life support (Manara, Murphy, and O'Callaghan 2012). When life support is withdrawn, it usually takes up to 60 minutes before circulation ceases. After circulation has ceased, a no-touch period follows where physicians must observe the patient to ensure that circulation and respiration do not resume spontaneously. Death is declared if no spontaneous resumption of circulation or respiration is observed during the no-touch period. Currently, most countries apply a five-minute no-touch period (Lomero et al. 2020). This means that physicians are required to observe the patient for a minimum of five minutes

after circulation has ceased before death can be declared and organs procured.

To clarify, having two criteria for the determination of death does not imply that an individual can be dead in different ways. As explained by the President's Commission when they introduced the two criteria in 1981:

It would be possible, as in the statute drafted by the Law Reform Commission of Canada, to propound the irreversible cessation of brain functions as the "definition" and then to permit that standard to be met not only by direct measures of brain activity but also "by the prolonged absence of spontaneous cardiac and respiratory functions." Although conceptually acceptable [...] the Canadian proposal breaks with tradition in a manner that appears to be unnecessary. [...] [B]iomedical scientists can explain the brain's particularly important and vulnerable role in the organism as a whole and show how temporary loss of blood flow (ischemia) becomes a permanent cessation because of the damage it inflicts on the brain. Nonetheless, most of the time people do not, and need not, go through this two-step process. Irreversible loss of circulation is recognized as death because-setting aside any mythical connotations of the heart-a person without blood flow simply cannot live. (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1981, 74)

This means that while an individual can be determined to be dead based on two different criteria, they are used to diagnose a singular phenomenon, namely the loss of the organism's capacity to function as an integrated whole (the interrelated system consisting of the brain, heart, and lungs), with the brain as the apex of the integrated system (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research 1981). When the criteria for determination of death requires irreversible loss of brain functions, or of circulatory and respiratory functions, it is because if neither of these functions are irreversibly lost, the capacity to function as an integrated whole is not lost and the individual is not dead. If e.g., circulation and respiration are resumed by medical intervention while brain functions are not irreversibly lost, the brain functions can return, and the organism will function as an integrated whole. Contrarily, if brain functions are irreversibly lost, resumption of circulation and respiration will not restore the individual to function as an integrated whole. Since circulation and respiration are missing neurological integration, the individual is dead. Similarly, if circulation and respiration are

irreversibly lost, but some brain functions remain, the organism can no longer function as an integrated whole. Even if brain functions are not yet irreversibly lost, the brain will deteriorate due to lack of blood flow, and they inevitably will be.

That these vital functions must be irreversibly lost means that they cannot be resumed, either by a spontaneous resumption of circulatory and respiratory function in the patient or by any medical intervention. Some have questioned whether patients enrolled in cDCD protocols are dead by the time organs are procured, because studies have shown that heart function, and thus circulation, can be reanimated beyond the no-touch period (Marquis 2010; Miller and Truog 2012; Rodríguez-Arias, Smith, and Lazar 2011). In addition, the protocols are criticized because the irreversible loss of all brain functions is not demonstrated and can only be assumed after this period (Rodríguez-Arias, Smith, and Lazar 2011). This concern has been further heightened by the use of extracorporeal membrane oxygenation (ECMO) to perfuse organs once death has been declared. When ECMO is used, it often involves the use of techniques to occlude the aorta and prevent reperfusion of the brain. The use of these techniques, which are currently applied in all cDCD protocols in Europe that allow ECMO (Lomero et al. 2020), raise questions about whether patients meet the requirement of irreversible loss of circulatory and respiratory functions, since these functions are restored, and thus are not irreversibly lost. Further, it is questioned whether brain functions are irreversibly lost since it is necessary to prevent reperfusion of the brain to avoid restoring brain function (Rodríguez-Arias, Smith, and Lazar 2011).

Contrarily, some argue that in the context of cDCD, irreversible loss of functions should be understood as permanent loss of functions (Bernat 2010; Huddle et al. 2008; Lizza 2020). Permanent loss of functions entails that functions cannot resume spontaneously in the patient and will not be resumed by any medical interventions. The argument from Lizza, Bernat, and Huddle et al. is that in cDCD protocols, the possibility of spontaneous resumptions is ruled out by the notouch period; furthermore, functions will not be restored by medical interventions. This means that we are certain that the patient will die if she is not already dead. They argue that since there is no intention of initiating resuscitative measures in the context of cDCD, "permanence" is a valid surrogate for "irreversibility" and can be used to determine death.

The debate on whether permanent or irreversible loss of functions is required to determine patients'

death clearly illustrates that many in the bioethical literature assume that a valid determination of death is a prerequisite if procurement of organs is to respect the dead donor rule. This assumption has also raised questions of whether the criterion for determination of death should be altered (Shemie et al. 2014), whether the no-touch period should be extended (Stiegler et al. 2012), and whether we should abandon the dead donor rule (Miller and Truog 2012).

While changing the definition of death is certainly an option, it should be considered with caution. If the public gets the impression that the definition of death is changed only to accommodate the growing need for organs, it might generate a general worry about whether physicians are only interested in harvesting organs. As a voluntary practice, organ donation is highly reliant on trust from the public, and if the attitude to organ donation changes toward being more skeptical, the number of organs available might decrease.

It might seem obvious that if uncertainty exists about whether the donor is dead following a fiveminute no-touch period, we could simply extend the no-touch period until we are certain that circulatory and respiratory functions or brain functions are irreversibly lost. This, however, raises two issues. First, the minimum period required to ensure the irreversible loss of these functions is not established (Ave, Shaw, and Bernat 2016; Shemie and Gardiner 2018). Second, extending the no-touch period would increase the time that organs are deprived of oxygen, known as "warm ischemia time," and increase the risk of graft failure in the recipient or the risk of organs not being viable for transplantation (Manara, Murphy, and O'Callaghan 2012; Marasco et al. 2012; Mathur et al. 2010).

Abandoning the dead donor rule has also been suggested. Franklin Miller and Robert Truog have argued that since almost no donors are known to be dead, we are left with the choice of abandoning organ donation or abandoning the dead donor rule<sup>2</sup> (Miller and Truog 2012). The issue with abandoning the dead donor rule is that it would make it acceptable for physicians to cause the death of patients by procuring their organs (Robertson 2014). This would depart radically from what is normally accepted in medical ethics, since it is in general considered morally wrong for

<sup>&</sup>lt;sup>2</sup>Miller and Truog argue that not only are cDCD donors not known to be dead, but the same goes for donors who donate after brain death is declared. We will not engage in this discussion here, but will only note that brain death is commonly accepted in the medical profession and in law.

physicians to intentionally cause the death of patients<sup>3</sup> (Veatch and Guidry-Grimes 2020).

All the above should show that the assumption that donors must be dead before procurement of organs is deeply entrenched in the debate over cDCD and its compatibility with the dead donor rule. It also shows that this assumption has stimulated responses as to how we should deal with the uncertainty about whether donors enrolled in cDCD protocols are dead that are at least questionable. We claim that the above discussion and responses are slightly misunderstood because they tend to focus on the validity of the criteria for determination of death instead of cDCD protocols compatibility with the dead donor rule. In what follows, we will argue that cDCD protocols do comply with the rule.

## THE DEAD DONOR RULE AND CDCD

It should be emphasized that what we defend in this paper is the standard cDCD protocol used in most countries where the procurement of abdominal organs follows from the withdrawal of life support and a fiveminute no-touch period after asystole. If respiration and circulation do not resume within the five-minute no-touch period, death is declared, and procurement of the donor's organs can begin (Manara, Murphy, and O'Callaghan 2012). As shown in the previous section, the debate about cDCD has primarily dealt with the question of whether patients are dead at the time organs are procured. Following Robertson's exposition of the dead donor rule, however, this is the wrong question to ask if we want to know if cDCD respects the rule. What we should investigate is whether organs necessary for life are procured in cDCD protocols, since the dead donor rule only restricts "removal of organs necessary for life [...] because removal of those organs would kill the donor." (Robertson 1999, 6). In what follows, we will argue that no organs necessary for life are removed in cDCD protocols. It should be clarified that we are not trying to establish whether physicians should be liable for the death in any legal sense, nor do we analyze whether procurement of vital organs in cDCD protocols can be considered the legal cause of a patient's death. We are merely investigating whether organs like the liver and kidneys are always necessary for life.

It is apparent that in many circumstances, organs are necessary for life and that procurement of them would cause death. If I sedate an otherwise healthy person and remove her liver, I will be removing an organ necessary for life. Had I not removed the liver, the otherwise healthy person would live on, presumably for a substantial period of time. Similarly, if procurement of organs from still-living patients prior to removal of life support, as suggested by Paul Morrissey (Morrissey 2012), was allowed, removal of the liver would at least sometimes imply removal of an organ necessary for life. Patients eligible for cDCD--that is, patients with catastrophic brain injury who are on life support but who cannot be diagnosed as dead based on the neurological criteria-have a very small chance of recovering to a satisfying quality of life following the withdrawal of life support (Miller and Truog 2012). Even though chances are slim, death does not always follow when life support is withdrawn. Therefore, procurement of a liver or both kidneys in this case, or at least in some of these cases, will be removal of organs necessary for life, and will cause the patient's death.

What about the standard cDCD protocols described above? Even if we accept the premise that uncertainty exists about whether the patients enrolled in these cDCD protocols are actually dead after the fiveminute no-touch period, we do know that this period is sufficient to ensure that the brain injury of the patient is in fact so severe that the patient cannot maintain circulation and respiration by herself. In a study of autoresuscitation in 73 cDCD patients, no cases of spontaneous resumption of circulation were reported after two minutes (Sheth et al. 2012). Similarly, a pilot study of 41 patients who had life support withdrawn in an intensive care unit showed no evidence of autoresuscitation after 89 seconds (Dhanani et al. 2014). It is also evident that neither brain function nor circulation and respiration will be restored by medical intervention since a decision to withdraw life support implies that the patient should not be resuscitated and the passage from life to death should not be interrupted (Huddle et al. 2008). If the patient is not dead after the no-touch period, she inevitably will be so a short time later. Given the implied request in withdrawal-of-life-support decisions to refrain from resuscitation, it would be both morally and legally dubious to initiate resuscitative measures following the no-touch period.

Once the point of possible autoresuscitation has passed, we are certain that the severity of the donor's brain injury has put her on an inevitable trajectory toward death. Because the possibility of circulation, respiration, and brain functions resuming

<sup>&</sup>lt;sup>3</sup>Not all agree to this since euthanasia or mercy killing is accepted some places; however, whether physicians should be part of such practices remains highly controversial.

spontaneously are ruled out, and because the functions will not be resumed by intervention, they will keep declining until they are lost irreversibly, if they are not already, and the patient will be dead. This means that the catastrophic brain injury of the donor will inevitably cause her to die. This is also how death is determined outside cDCD protocols, as explained by Huddle et al:

We make a diagnosis of death shortly after cardiorespiratory arrest in the DNR patient not because we can make the diagnosis with absolute certainty within five minutes thereafter, but because we are willing to tolerate some diagnostic imprecision in the context of a passage from life to death that we have determined not to interrupt. (Huddle et al. 2008)

At this time, the patient has arrived at a point in the process of dying where we are sure that the condition of the patient is no longer consistent with life. Therefore, death is determined despite the fact that some potential for brain or circulatory function might remain. When a patient has arrived at this point in the process of dying, it can no longer be claimed that organs are necessary for life. If organs are procured, the patient dies; if organs are not procured, the patient still dies. Once the no-touch period has excluded autoresuscitation, organs like the kidneys or the liver are no longer necessary for life because life will not persist. This is not to argue, as others have done, that we could now consider functions as irreversibly lost and with certainty claim that the determination of death is valid. Neither is it to claim that procurement of vital organs from patients enrolled in cDCD protocols cannot be morally wrong for other reasons, e.g., if consent is not properly obtained. We simply argue that procurement does not conflict with or violate the dead donor rule under these circumstances.

# THE DEAD DONOR RULE AND NORMOTHERMIC REGIONAL PERFUSION

Often in cDCD protocols, organs are not procured directly after the no-touch period. Many protocols involve the use of organ-preserving techniques like ECMO (Lomero et al. 2020). A study from 2019 indicates that the use of such organ-preserving techniques in liver donation reduces the rate of biliary complications and graft loss and authorizes successful liver transplantation from older donors (Hessheimer et al. 2019). Although the use of ECMO seems promising for providing more viable donor organs and lessens at least some of the complications a recipient could experience after transplantation, the technique is sometimes questioned for its compliance with the dead donor rule.

When ECMO is applied, blood from the donor is pumped into an extracorporeal circuit where the blood is oxygenated and carbon dioxide removed before the blood is returned to the patient's circulatory system (Ave, Shaw, and Bernat 2016). In other words, ECMO restores oxygenated blood flow in the patient. This raises two concerns. First, some worry that the use of ECMO might restore brain functions and thus revive the patient (Ave, Shaw, and Bernat 2016). Second, some argue that because circulatory function and brain function can be restored, the patient is not dead (Rodríguez-Arias, Smith, and Lazar 2011). The latter of these worries does not concern the dead donor rule. As described, the dead donor rule only restricts organ procurement from causing the death of the donor, it is not a prerequisite that the donor must be dead. However, the former concern might be problematic in regard to respecting the rule.

Our argument for why procurement of vital organs does not cause the death of the donor in cDCD is based on the assumption that the inevitable trajectory toward death caused by the catastrophic brain injury—that is, permanent loss of circulatory, respiratory, and brain functions that will not be restored—precedes the procurement of organs, and thus that these organs are no longer necessary for life. If ECMO is used and oxygenated circulation to the brain is restored, then this might no longer be the case. It could at least be argued that as circulation is reanimated, the patient once again functions as an integrated whole, and thus organs can be seen as necessary for life.

However, when ECMO is used in cDCD protocols, it is not the entire circulatory system of the patient that is supplied with oxygenated blood. Instead, only the abdominal cavity is perfused (Hessheimer et al. 2019). This method or technique is called normothermic regional perfusion (NRP). When NRP is used, circulation is reestablished but blood flow to the heart and brain is cut off by ligating the aortic arch vessel. Except for in the U.K., where hearts are sometimes procured, this is the procedure applied by all European countries that allow NRP in their cDCD protocols (Lomero et al. 2020). Limiting reestablished blood flow to the abdominal cavity prevents oxygenated blood from reaching the brain and the heart and ensures that the organism does not resume its function as an integrated whole. The trajectory toward death proceeds as it would have had ECMO not been used. In other words, this procedure does not alter the fact that the patient's condition is inconsistent with life, and thus, organs do not become necessary for life. As put by Parent et al.:

Ligating vessels to maintain absence of brain blood flow enables the goal of WLST<sup>4</sup>—accepting the patient's death—and the wish to donate organs. [... It] ensures natural progression to complete cessation of brain function, so as to save other lives through organ donation (Parent et al. 2020, 4).

This apparently makes the use of NRP in cDCD protocols compatible with the dead donor rule. There is, however, an important difference between cDCD protocols with and without NRP. When NRP is not utilized, the inevitable trajectory toward death is free from interventions by physicians. When NRP is applied and vessels ligated, physicians actively ensure that cerebral blood flow is not reestablished. Were it not for the ligation, the trajectory toward death could have been interrupted and the organism could theoretically have been restored to function as an integrated whole. Thereby, we are not saying that the donor would recover to live a satisfying life were it not for the ligated vessel, but merely that the ongoing demise of circulatory and brain function would have been interrupted, at least temporarily.

What remains is that NRP does not change the progress toward death when reperfusion of the brain is prevented. Qua the implicit requirement in withdrawal of life support, that patients not be resuscitated, the organism is not restored to constitute an organism that functions as an integrated whole before organs are procured, even if the potential is still there. Occlusion of the vessels, in this case, will merely ensure that the demise of the organism continues as it would have in other cases of withdrawal of treatment where cDCD is not involved. With this in mind, cDCD protocols, even involving NRP, do not violate the dead donor rule.

On a few occasions, it has been reported that techniques for ligating vessels have not been successful. In a cDCD procedure in France, where an aortic occlusion balloon was used, a patient suddenly began to gasp after initiation of NRP (Ave, Shaw, and Bernat 2016). These unforeseen gasps from the patient were due to a malfunction in the aortic occlusion balloon used in the procedure, and such technological deficiencies should, of course, be corrected before we can be certain that the use of NRP complies with the dead donor rule.

<sup>4</sup>Withdrawal of life-sustaining treatment.

#### CONCLUSION

We have argued that the ongoing debate about whether donors enrolled in cDCD protocols are dead or not, is a different discussion from whether cDCD protocols comply with the dead donor rule. The rule is often misunderstood as requiring that donors must be dead before procurement of organs can take place. This is not exactly true. The rule only requires that organ procurement does not cause the death of the donor. In this light, it seems that the currently utilized cDCD protocols, where a five-minute no-touch period is applied, do not violate the dead donor rule, even if there are some scholars who claim that the donor is not completely dead after a five-minute no-touch period. Donors enrolled in such protocols will already be subject to a lethal pathophysiological state that has sent them on a trajectory toward death and that cannot be retracted by the donor herself and will not be retracted by medical intervention. Under these circumstances organs are no longer necessary for life, and procurement of them will not cause the donor's death. Even though other norms or principles in medical ethics, as well as the legal framework in certain countries, might restrict procurement from cDCD donors, the dead donor rule does not do so.

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