# The Canadian Council for Donation and Transplantation on

Donation after Cardioculatory Death

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The Canadian Council for Donation and Transplantation (CCDT) in 2006 released its recommendations for what it terms “donation after cardiocirculatory death” (DCD),[[1]](#endnote-2) which is elsewhere and more commonly called “non-heart-beating organ transplantation.” These recommendations are designed to "promote patient-care-based principles for providing the option of donation within a sound ethical framework and to provide guidance to individual programs in developing parameters of safe practice in this field."[[2]](#endnote-3) Two of the most asked questions by families considering DCD are: "Is my loved one really dead?” and "Will he or she feel any pain?"[[3]](#endnote-4) It is thus reasonable to suppose that any acceptable DCD program will either enable one to answer those questions with a flat "Yes" and "No," or if not, put families in a position to make an informed choice as to whether to proceed with the donation. I will argue in what follows, however, that DCD programs set up on the recommendations of the CCDT will not do either of these things, and hence fail to satisfy consent requirements.

The critique I offer comes from an ethical rather than legal point of view. What the law in this area is cannot be decisively determined until the courts pronounce on it, and is in any case clearly overshadowed by ethics. Transplant centers with a commitment to ethics cannot proceed with programs that do not pass ethical muster, whatever the law may allow. Nor would it be wise, from a purely prudential point of view, for centers that depend vitally on public trust to act in ways that the public would regard as unethical. I direct my arguments specifically at the CCDT’s report, but as its recommendations are identical to those of the Institute of Medicine (IOM),[[4]](#endnote-5) they apply equally to that report as well.[[5]](#endnote-6) My aim is not to oppose DCD programs, but to emphasize the importance of consent, and put centers that have or are planning such programs in a better position to design them.

**Consent to donation after cardiocirculatory death**

The central recommendation of the CCDT’s report concerns the determination of death for purposes of DCD. Under Canadian law, the report explains, "death shall be determined by two physicians in accordance with ‘accepted medical practice’."[[6]](#endnote-7) Neurological death has long been accepted in Canada (as in the rest of the Western world) as death for purposes of heart-beating organ transplantation. Such transplantation involves patients who have suffered a catastrophic brain injury, been ventilated, declared dead by neurological criteria, and had their vital functions maintained mechanically until the point of transplantation. To limit transplantation to these patients, however, severely limits the donor pool. The idea behind DCD is to expand that pool by including in it patients who are in hopeless conditions but are not dying because of brain injury, and hence will not suffer the neurological death necessary to become heart-beating donors. As long as we continue to hold the so-called "dead donor rule," according to which dying donors cannot have their organs taken before they are dead, this requires that death for non-brain-injured patients be able to be declared by alternative criteria, specifically by cardiocirculatory criteria.[[7]](#endnote-8)

There is nothing new about determining death by cardiocirculatory criteria; indeed, the majority of deaths are declared on that basis. But since, before the advent of DCD, there was no pressing need to assign a precise time to when death declared in this way occurred, the interval between the cessation of heartbeat and breathing and the declaration of death was never specified. “Prolonged cessation” served well enough. For DCD programs, however, where it is important to minimize warm ischemia time and also not violate the dead donor rule, the exact interval required becomes a matter of importance. The CCDT recommends that for purposes of DCD the following criteria must be met before organ procurement:

1. Beginning with the onset of circulatory arrest, a 5 minute period during which the absence of palpable pulses, blood pressure and respiration must be continuously observed by at least one physician; and
2. Death is determined by two physicians by documenting the absence of palpable pulses, blood pressure and respiration upon completion of this 5 minute period.[[8]](#endnote-9)

This recommendation of a 5 minute interval lies at the conservative end of other proposals, which range from no waiting period to waiting periods between 2 to 5 minutes,[[9]](#endnote-10) and falls short of the 10-15 minutes estimated for death determined by cardiocirculatory criteria to coincide with death determined by neurological criteria.[[10]](#endnote-11) It is not perfectly clear that the recommendations of the CCDT based on a single forum constitute “accepted medical practice.”[[11]](#endnote-12) If it does, however, the CCDT can validly conclude that, from a legal point of view, death determined by cardiocirculatory criteria is death for purposes of DCD.

There is no problem in recalibrating the criteria for the determination of death to facilitate organ transplantation. That was done when neurological criteria for the determination of death were accepted, and it can be done here. There would likewise be no problem if death determined by cardiocirculatory criteria and death determined by neurological criteria were just different ways of identifying the same state. But, as noted above, this is not so. Death determined by neurological criteria coincides with death in the ordinary sense of the word, namely, a state in which a person has no respiration or heartbeat, will not regain these spontaneously, and it is not physically possible to restore them by artificial resuscitation. But the state identified as death by the CCDT’s cardiocirculatory criteria is not known to be irreversible in this sense. The IOM (which also recommends a 5 minute interval) claims that “existing empirical data cannot confirm or disprove a specific interval at which the cessation of cardiopulmonary function becomes irreversible.”[[12]](#endnote-13) The CCDT comments that its literature review could not identify any evidence base for claiming that either autoresuscitation can occur or artificial resuscitation can succeed after the 5 minute interval.[[13]](#endnote-14) But, given the limited number of studies that have been done, this does not show that those things are impossible, and hence this absence of evidence does not—nor does the CCDT anywhere—contradict the IOM’s view. As long as that view is uncontradicted, however, even if further investigation were to show that patients are dead in the ordinary sense after the 5 minute interval, that is not something that we know now. The fact thus remains that organ retrieval at death determined by the CCDT’s cardiocirculatory criteria will begin before death in the ordinary sense can be known to occur.

This, however, does raise a problem. In fact, it raises two. One concerns whether the CCDT violates the dead donor rule,[[14]](#endnote-15) but I set this aside, and assume that there is some sense in which death determined by the CCDT’s cardiocirculatory criteria really is death.[[15]](#endnote-16) Nonetheless, as that sense is different from the ordinary sense, we get a second problem. This concerns consent, and will be my target. No problem about consent would arise from the discrepancy if patients or families were told that and how death determined by cardiocirculatory criteria differs from death as ordinarily understood. But the CCDT does not say that they must be told this. Once patients or families are told that death will be determined by those criteria, and what that involves, there is no requirement that further information about the nature of the state identified as death be routinely given. Consent to organ donation at death is, without further ado, taken to be consent to organ donation at death determined by cardiocirculatory criteria, and it is this silence that gives us the problem about consent. By consenting to organ donation at death, patients or families will expect organ retrieval to take place when the patient is known to be in a physically irreversible state. By having death determined by cardiocirculatory criteria, organs will be retrieved before the patient is known to be in such a state. The problem is how consent to organ retrieval when one is known to be in a physically irreversible state can be taken to be ethically valid consent to organ retrieval when one is not known to be in such a state.

The whole point of seeking consent in organ procurement is to allow individuals to decide what shall and shall not be done with their or their loved one’s bodies. This requires that people understand what they are consenting to, and that means that ethically valid consent must be informed. Without this, transplant teams do not have the moral authority to proceed with organ retrieval. Perhaps the CCDT (which does not acknowledge any problem about consent) would argue that reasonable people interested in DCD would not care how death determined by cardiocirculatory criteria differs from death in the ordinary sense, and hence that this information need not be disclosed. But this is a singularly implausible response. It cannot be doubted that many people attach religious, cultural, metaphysical, or aesthetic significance to the time of death, where the only concept of death they have is the ordinary one. Others may fear that starting organ retrieval before the patient is dead in the ordinary sense—and hence before meeting the neurological criteria for death—will cause distress. (We will return to this in the next section.) Still others may not care about either of these things, but simply not like the idea of being led to think organ retrieval will occur at one time when it will occur at another. There is thus ample reason to think that consent to organ donation at death cannot be taken to be informed consent to organ donation at death determined by the CCDT’s cardiocirculatory criteria.[[16]](#endnote-17)

Given this, as long as the CCDT retains its commitment to proceed with ethically valid consent, it must do one of two things. It can either increase the 5 minute interval to a time when physical irreversibility can be assured (and it is sometimes argued that this would not greatly reduce the number of usable organs),[[17]](#endnote-18) or disclose that and how death determined by cardiocirculatory criteria differs from death as ordinarily understood. Doing the latter will certainly complicate the recruitment of organ donors, and may diminish their number. But even if fewer organs were to result—and we cannot be sure of this; the public might respond well to a fully transparent DCD program—if organ retrieval requires informed consent, and that requires greater transparency than the CCDT mandates, that greater transparency must be provided. Physicians provide complicated information to patients and families at times of grief elsewhere when informed consent is required (as, for example, when the question is whether to terminate life-sustaining treatment), and it is not clear why seeking consent to DCD should proceed on different principles.

**Distress**

I now turn to the second in way in which the CCDT’s recommendations fall short. There is significant scope for the possibility of distress during DCD. Controlled DCD may involve pre-mortem and pre-withdrawal of life-sustaining therapy interventions such as vessel cannulation, and post-mortem interventions such as in-situ preservation.[[18]](#endnote-19) Uncontrolled DCD may additionally involve both pre-consent and/or post-consent chest compressions and mechanical ventilation.[[19]](#endnote-20) Both controlled and uncontrolled DCD will also typically call for the withdrawal of life-sustaining treatment. We know that all these interventions will cause distress to conscious patients who are not on palliative medications. Is it possible that they will also cause distress to patients declared dead by cardiocirculatory criteria, and if so, what should be done about that? .

There are three approaches that can be taken. (1) Provide palliative medications when there are physical signs compatible with distress; (2) withhold all such medications on the ground that even if distress is occurring the patient does not have sufficient cognition to interpret any sensations as noxious; (3) prophylactically premedicate to prevent any possible distress.[[20]](#endnote-21) There is no consensus on the appropriate approach, and the CCDT (along with the IOM) does not recommend one. Instead, it proposes that the management of the dying process, including procedures to withdraw life-sustaining treatment, sedation, analgesia, and comfort care should proceed according to the existing practices of individual ICUs.[[21]](#endnote-22) What those practices are in the case of DCD in Canada remain to be developed, and if that development parallels what has happened elsewhere, we can expect variations from centre to centre. This would be a matter of indifference, and the CCDT's approach the appropriate one, if there were nothing to choose between the expected variations. But this is not so. As we will see, any protocol other than (3) is faced with fatal problems.

The most common distress-protocol for DCD is perhaps (1), where medication is provided contingent on signs compatible with distress. The Pittsburgh protocol, for example, stipulates that: “If narcotics and sedatives are administered, these drugs must be titrated to the patient’s need for provision of comfort. The administration of clinically appropriate mediations in appropriate doses to prevent discomfort is acceptable, with titration of medication predicated on signs compatible with distress.”[[22]](#endnote-23) The problem with such protocols is that they do not guarantee that organ donors will not experience distress. To have a distress protocol at all is to grant that DCD may involve distress to the patient, and to medicate only on signs suggestive of distress is to expose patients to the possibility of experiencing it. But if distress (however transitory) might occur, the possibility must be disclosed, for that is surely information that anyone would want to know before agreeing to DCD. Disclosing it, however, is not something any DCD program can do if it expects to flourish.

Protocols of type (2) do not fare any better. It is highly speculative to claim that patients declared dead by the CCDT’s cardiocirculatory criteria are in such debilitated conditions that they would not be able to experience distress as noxious. It may be true that when such patients exhibit signs compatible with distress they feel nothing objectionable. But no one can know this, and many—all those who subscribe to protocols of type (1), for instance—do not think it is true. Nor can the possibility of distress be excluded by saying that such patients are dead, and thus are insentient. It is arguable that patients declared dead by neurological criteria do not feel anything, for there is an absence of brain function in such cases. But as brain function may be present in the case of death determined by cardiocirculatory criteria, such patients lack the very feature that gives us reason to think that dead patients do not feel anything. Thus centers that adopt protocols of type (2) are faced with the same invidious alternatives as are centers that adopt those of type (1), namely, to either disclose the possibility of distress (and thereby deter donation), or not disclose that possibility (and thereby violate ethical requirements).

Nor would consent problems disappear even if full disclosure did not deter donation. Patients themselves, on hearing about the possibility of distress, can choose to run that risk. But the bulk of consent for DCD will be sought from families, and it is not clear that a family can consent to that on behalf of a loved one. For to do that, it is not enough that *the family* thinks that running the risk would be a good thing. They must have some reason to think that *their loved one* would want to run the risk. This would be straightforward if the loved one had directly communicated that willingness to them. But in the absence of that surely rare event, it is not at all straightforward, because then the family must infer the willingness from something else, and it is not clear what that could be. They cannot infer it from the desire to be an organ donor. For that is usually believed to be a procedure that does not involve any distress, and we cannot infer the desire to undergo a procedure that carries the risk of distress from the desire to undergo one that is not believed to have such a risk. Nor is it easy to identify anything else that would enable the families to confidently say that their loved one would want to undertake that risk.

The upshot is that any protocol that does not entirely eliminate the possibility of distress will raise seemingly insurmountable ethical problems whether or not full disclosure about that possibility is made, and this points us towards (3) as the protocol of choice. However, this protocol is also not without difficulty. The problem is that providing pain medication may hasten death, and the law allows for hastening death if and only if that is a collateral effect of providing medication necessary to quell distress. Those who follow protocols of type (1) can defend themselves against a charge of wrongfully hastening death by pointing to the signs suggestive of distress that trigger the delivery of medication. For those signs provide evidence that if the medication were not provided the patient would be in distress. But those who follow (3) cannot make such a defense because the whole point of (3) is not to allow any distress to occur at all, and hence there (ideally) will never be any signs of distress. The aim of that protocol is not to medicate only when the patient *would* otherwise be in distress, but to so when the patient *might* otherwise be in distress. This aim is no doubt beneficial for the patient, but makes it harder for physicians to defend themselves against accusations of wrongdoing.

Providing prophylactic medication does not always or even typically hasten death. But the mere and undeniable possibility that it might is enough to raise the spectre of criminal charges, civil suits, investigations by professional bodies, and the censure of colleagues and the public that cannot be easily answered. Nonetheless, however chilling all this may be, it is not sufficient to make centers reject protocol (3). For the alternatives are (1) or (2), and we have seen that those will make any DCD program either unethical (if it does not disclose the possibility of distress) or impossible (if it does). It is thus important that the CCDT not leave the choice of distress protocols open, but point centers in the direction of (3). It is all the more important for it to do this both to give the practice of prophylactic premedication its stamp of legitimacy, and because centers will predictably be tempted to adopt other protocols.

**Conclusion**

Since the publication of the CCDT’s recommendations more and more centres in Canada are providing for DCD, and the advent of such programs is to be enthusiastically supported. But the CCDT’s recommendations are poor ethical guides to developing them, and it is up to centers that are planning DCD programs to make the necessary modifications. Specifically, given the foregoing, they must do two things. The first is to ensure that patients or families interested in DCD do not have any misapprehension about when organs will be retrieved. This can be achieved by either disclosing that and how death determined by the CCDT’s cardiocirculatory criteria differs from death in the ordinary sense, or altering those criteria so that there is no divergence. The second is to put in place a distress protocol which guarantees that organ retrieval does not carry any risk whatsoever of distress. Only with these conditions will there be a DCD program that will make patients and families full partners in the enterprise to close the gap between the supply and demand of transplantable organs.

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