LIMITING DONATION AFTER CARDIAC DEATH: QUESTIONS ON CONSENT

Blake A. Chapman

I. INTRODUCTION

In an effort to overcome a virtually insurmountable organ shortage, various organ procurement organizations, with the support of physicians, have revived an old donation paradigm, “donation after cardiac death” (DCD), without fully considering the ethical and legal implications. This paper argues that the results of this ill-considered haste to push DCD as a new donation option are consent mechanisms of questionable legal authority, particularly concerning the role of substitute decision-makers (SDMs). In particular, this paper demonstrates that even with explicit consent and donation legislation, there remains an unfortunate legislative void regarding the ability of SDMs to consent to DCD pre-mortem interventions. The result of such a gap is a fall-back to the common law, which eliminates the ability of SDMs to consent to treatments on a donor’s behalf, except in cases of minors. This void creates a clear and present need for new legislation or regulations to clarify the role and responsibilities of SDMs, failing which DCD protocols should be curtailed. The use of organ donation cards as prior consent for DCD will also be demonstrated as inadequate and arguably without legal grounding. While the primary focus of this paper is Ontario, the ethical and legal issues examined here are being grappled with in many jurisdictions.

This paper begins with an exploration of the history of DCD and the brain death standard, which DCD now seeks to supplement. One of the first re-introductions of DCD into medical practice – the Pittsburgh Protocol – will be used as a central template to explore the general development of DCD protocols. Attention will also be paid to the rationale behind the DCD
push, as well as the need for a definition of death embodied by the dead donor rule. Next, the history of DCD in Canada will be examined, with an eye to developments from a pan-Canadian medical forum on DCD, as well as critiques of the national forum itself. In addition, the details of recent Canadian DCD protocols will be reviewed, primarily Ontario’s Trillium Gift of Life Network. The protocols will be examined for legal and ethical issues concerning donor consent to procedures ancillary to the donation process. Finally, the legal role of SDMs will be probed given the legislative uncertainty surrounding their ability to consent to pre-mortem interventions in the donor’s “best interests”.

II. DCD DEVELOPMENT

A. Brain Death and the Return to DCD: The Pittsburgh Protocol

DCD is not a new donation paradigm, but a revived version of non-heart-beating donation (NHBD). NHBD was the only method of organ donation used up until the late 1960s, when it was replaced by organ donation programs founded on the neurological criteria of brain death. In 1968, the Ad Hoc Committee of Harvard Medical School to Examine the Definition of Brain Death (Harvard Committee) recommended a new definition of death contrary to the standard practice at that time of cardiopulmonary death, or cessation of heart beat and respiration: brain death. The switch in standards to define and determine death was primarily triggered by developments and improvements in resuscitation efforts and life-support systems that rendered the cardiopulmonary standard inadequate. New technologies can resuscitate and maintain a patient on a cardiopulmonary basis when that patient has no hope for continued brain function. Thus, using the brain death stan-


standard, a patient can be declared dead and, with his or her prior consent or the SDMs’ consent, the brain dead patient’s organs may be transplanted.

DCD regained the spotlight in the U.S. in 1993, when the University of Pittsburgh Presbyterian Medical Center created and adopted a protocol (Pittsburgh Protocol) for NHBD. The Pittsburgh Protocol calls for the use of the cardiopulmonary criteria to declare death. The Protocol does not require complete irreversibility, as the heart could still be resuscitated after it stops beating if it were not for the overarching presence of a do not resuscitate (DNR) order. Patients are thus declared dead because they or their SDMs refused resuscitation. Under the Protocol, patients are declared dead after two minutes of pulselessness, which may itself take some time to set in after the withdrawal of life sustaining treatment via ventilators, pump machines, etc. The Protocol assumes that if the heart has not restarted spontaneously after two minutes, it will never do so, and thus the patient is irreversibly dead. This also eliminates the prospect of the organ procurement procedures being the cause of the patient’s death. Several other organ procurement organizations use the two minute standard, although a five minute waiting period is also widely accepted. A pan-Canadian Forum (the “Forum”) held by the Canadian Council on Transplantation and Donation recommends a five-minute waiting period after the onset of cardiac arrest, a standard which has also been adopted by the Trillium Gift of Life Network in Ontario. Truog, a pediatric critical care physician, contends that two minutes of pulselessness is insufficient to guarantee that the patient is in fact brain

5 Ibid.
6 Mohamed Y. Rady, Joseph L. Verheidje & Joan McGregor, “‘Non-Heart-Beating’ or ‘Cardiac Death’ Organ Donation: Why We Should Care” (2007) 2 Journal of Hospital Medicine 324.
dead. On the other hand, the Institute of Medicine notes that a protocol requiring a lack of spontaneous reanimation after two minutes exceeds the ordinary medical practice where there is no fixed period specified, because brain function ceases fifteen seconds after circulation to the brain is cut off. Nonetheless, the Institute of Medicine recommends a five minute period after cessation of cardiac function for certainty, to be confirmed by an EKG, arterial pressure and general unresponsiveness.

The discussion in some protocols of “irreversibility” is also a subject of debate, because while the heart may have irreversibly stopped in relation to spontaneous restarting, it may not have irreversibly stopped in the sense that it can never be restarted. There is an important distinction to be made between ‘legal irreversibility’ and ‘physiological irreversibility’. With medical interventions and “heroic measures”, it is possible that, in some cases, the heart may still be restarted by medical staff after the two minute waiting period has elapsed. There are also some concerns in the literature about the rare chance of a Lazarus Phenomenon; there have been rare reports of patients auto-resuscitating after more than ten minutes of cardiac asystole (absence of heart beat). Rady and colleagues argue that given the mere possibility of a Lazarus Phenomenon occurring, the waiting period should be extended, perhaps to ten minutes. The authors point to data establishing that the additional waiting time did not ultimately compromise the quality of the organs procured. More fundamentally, Rady and colleagues argue that the reported reoccurrence of ‘reanimation’ demonstrates that DCD violates the legislative definition of death in the model Uniform Determination of Death Act (UDDA) because the condition of the patient is not truly

---

9 Institute of Medicine, Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement (Washington, D.C.: National Academy Press, 1997) at 59 [IOM, Medical and Ethical Issues].
12 Rady, Verheidje & McGregor, supra note 6 at 325.
13 Ibid at 327.
‘irreversible’. Youngner and Arnold similarly note that waiting ten minutes after cardiac cessation is necessary for brain death to set in and ensure that the brain is not still alive when circulatory death is declared. They also argue that without extending the waiting period to ten minutes, organs will be removed from patients who are “probably dead”, “practically dead”, and “as good as dead”, and not only from those who are “certainly dead.” In general, Doig and Rocker worry that the lack of a common standard among organ procurement organizations may be an obstacle to expanding DCD programs. However, at least in Canada, the pan-Canadian nature of the Forum ensures that its decision on this issue represents at least a majority of Forum participants.

**B. Categories of DCD: Controlled & Uncontrolled**

DCD can be divided into two broad categories – controlled and uncontrolled. The former takes place in circumstances where the death of the patient is managed and planned, for example, when the patient is on life support machines in the ICU or is put on life support machines immediately after suffering a cardiac arrest while being monitored. The “controlled” aspect of the donation arises because the family and medical staff plan the manner, timing and place of the removal of life support. After death is pronounced, the deceased’s organs intended for donation are removed. “Uncontrolled” donations occur often when would-be donors suffer cardiac arrest outside


16 *Ibid.* at 73.


19 It seems unfortunate that the medico-legal community has chosen to adopt the term “uncontrolled” as it may have negative implications from a public relations perspective. To many lay observers, “uncontrolled” may denote chaos or a lack of authority or understanding on behalf of the supervising health care professionals.
a hospital and decisions are made about the discontinuation of CPR. As will be seen below, uncontrolled DCD has its own special set of ethical and legal issues, but is also reportedly the largest source of potential for increasing donations.\textsuperscript{20} It is perhaps for this reason that the Forum recommended that practices for controlled DCD be attempted and established before even considering moving on to uncontrolled donations.

The Maastricht University in the Netherlands has developed a grading system whereby DCD patients are split into four sub-groups for the purposes of classification.\textsuperscript{21} Maastricht I patients are those that are dead on arrival; Maastricht II patients have been subject to unsuccessful resuscitation efforts; Maastricht III patients are awaiting cardiac death, and; Maastricht IV patients are brain-dead donors who have suffered cardiac arrest. As can be seen, Maastricht I and II patients would be subject to uncontrolled DCD, while Maastricht III and IV patients would be subject to controlled DCD. The Forum declared that the terms controlled and uncontrolled should replace the quad-partite Maastricht classification for enhanced clinical practicability.\textsuperscript{22}

C. The Rationale for DCD

It is estimated that adopting DCD protocols across Canada could increase the supply of organs available for transplantation by anywhere from 20-50\%,\textsuperscript{23} and up to 72\% in pediatric donations.\textsuperscript{24} The anticipated increase is greatest amongst pediatric patients because approximately 75\% of deaths in pediatric ICUs are planned withdrawals of care.\textsuperscript{25} In such circumstances, patients are rarely, if ever, “brain dead”, yet they would be potential donor candidates under DCD. In addition, worldwide leaders in DCD, such as Japan and Holland, have shown that DCD can be the major, if not the sole source, of

\textsuperscript{20} IOM, Medical and Ethical Issues, supra note 9 at 25.
\textsuperscript{21} Ibid.
\textsuperscript{23} Doig & Rocker, supra note 17 at 1071, and; Youngner & Arnold, supra note 15 at 70.
\textsuperscript{25} Ibid.
The re-emergence of DCD can in part be attributed to the decreasing incidence and severity of traumatic brain injuries, which has resulted in fewer brain death patients whose organs would be suitable for donation. Similarly, Baker and colleagues point to data suggesting that brain death itself is on the decline because patients are kept alive with aggressive care management in the ICU. Youngner and Arnold argue that scientific improvements in limiting organ deterioration have led to increased viability of organs procured under cardiac death protocols. Thus, by adopting DCD as an acceptable donation protocol, the donor pool would be broadened to include not only brain dead patients but additional potential donors who do not meet the traditional brain death criteria. Knoll and Mahoney observe that statistically, the long term survival rates of renal transplants under a DCD protocol are similar to those transplants performed under a brain death protocol, and thus the decreased organ yield may only be artificial.

Truog notes that the cardiopulmonary standard is the standard that the non-medical portion of society readily and widely accepts. This is evidenced by its universal use for determining when someone can be cremated and buried. In fact, even the majority of medical practitioners still use the cardio-circulatory definition instead of brain death, in non-donation cases. In addition, the cardiopulmonary criteria is proffered as a common denominator that virtually all cultural and religious groups could find acceptable. However, Truog’s view is countered by a report on religious views in relation to non-heart-beating organ donation.

27 Doig & Rocker, supra note 17 at 1070.
29 Youngner & Arnold, supra note 15 at 70.
31 Truog, “Is it Time?,” supra note 8 at 35.
32 Ibid.
33 Patricia Hluchy, “When Brain Death Isn’t Terminal” The Toronto Star (13 April 2008).
to DCD by the Forum, which found, for example, that Christian denominations uniformly favour neurological determination of death (and, presumably also accept the cardiac death definition).  

Truog’s preference for the cardiopulmonary criteria for determining death is buttressed by his view that the only purpose of the brain death concept is to procure organs for transplantation, and thus should be viewed with skepticism, or at least from a critical perspective. Truog argues that without the need for increased donation, the brain death standard would never have been recognized or as widely accepted. The economic savings in the form of ICU bed availability, less medical care time spent caring for “hopeless patients” and increased numbers of organ donors all played a role in justifying the brain death standard being adopted because hospitals and transplant centers had academic and economic interests hindered by organ shortages. Ozark and DeVita are concerned that these factors, which may have contributed to the brain death push decades ago, may be reappearing in the modern case for DCD.

D. Canadian Protocol Development

In Canada, DCD has been slow to develop when compared to the U.S. The Canadian Council on Donation and Transplantation hosted a National Forum on DCD in February 2005 (the aforementioned Forum), with representatives of Canadian physicians, health care workers and other stakeholders. Their report and recommendations were ultimately published in the Canadian Medical Association Journal, with the majority of Forum participants supporting proceeding with DCD. The Forum’s stated purpose was to determine whether they could, “…offer DCD while maintaining the fundamental principles that preserve patient and family interests and professional standards.” Modern Canadian experience with DCD began in practice when the Ottawa Hospital announced it had performed the first DCD

36 Truog, “Is it Time?,” supra note 8 at 29
37 Ibid.
38 Ozark & DeVita, supra note 26 at 168.
39 Shemie et al., supra note 7 at 9.
transplantation under the new protocols in June 2006.\textsuperscript{40} DCD has been, and will likely continue to be, slowly adopted in Canada because of a lack of education in the area, the prevalence of ethical concerns and the unavailability of necessary resources.\textsuperscript{41}

Numerous commentators, Doig perhaps the most vocal of them, have dismissed the recommendations made and the report issued by the Canadian Forum for its lack of depth and breadth. Doig argues that more than a single forum is necessary to justify proceeding with DCD cross-country.\textsuperscript{42} In support of this argument he cites a study by Cook and colleagues that examined Canadian ICU standardized scenarios where physicians were asked to choose between treatment options ranging from full management, through limited interventions, to complete withdrawal of life sustaining treatment for twelve case scenarios.\textsuperscript{43} The authors of the study distressingly concluded that only in one of the twelve scenarios presented was the same course of treatment option chosen by more than 50\% of the physicians queried.\textsuperscript{44} While none of those scenarios specifically involved DCD, Doig infers that such a lack of consensus raises the specter of inconsistent decision-making in DCD cases – not a positive outlook for adopting such a publicly sensitive protocol.

Generally, Doig argues that the development of DCD policies should be initiated by individuals external to the transplant community, such as other physicians and members of the public, in order to ensure there are no conflicts of interest.\textsuperscript{45} This sentiment is echoed by Truog, who believes that closed-door policy development by physicians gives the appearance that, “…physicians involved are only too willing to draw the boundary between life and death whenever it happens to maximize the chances for organ procurement.”\textsuperscript{46}

Thus, an ideal protocol development system should be in place that removes

\begin{flushleft}
\textsuperscript{40} CTV News Staff, “Ontario Organ Pool to Include Heart Failure Victims” \textit{CTV News} (27 June 2006).
\textsuperscript{41} Knoll & Mahoney, \textit{supra} note 30 at 302.
\textsuperscript{42} Christopher J. Doig, “Is the Canadian Health Care System Ready for Donation after Cardiac Death? A Note of Caution” (2006) 175 Canadian Medical Association Journal 905 at 905.
\textsuperscript{44} Doig, \textit{supra} note 42 at 905.
\textsuperscript{45} Ibid. at 906.
\textsuperscript{46} Truog, “Is it Time?,” \textit{supra} note 8 at 34.
\end{flushleft}
any individual incentives to prematurely define death. Protocol development should also be broad-based and not consist solely of physicians and other health care professionals. Once a protocol is agreed upon, as the Forum ostensibly did, more must be done to notify the public that DCD is an accepted practice, that it does occur (with attendant implications for donor cards, as will be discussed below), and to explain the benefits of DCD. Bernat and colleagues believe that public messaging is a necessary ingredient for DCD to become more generally accepted. They believe that such messages should say that: (i) DCD honours donor patient’s wishes, (ii) DCD can provide comfort and support to donor families, and (iii) DCD saves lives.47

E. The Need to Define Death: The Dead Donor Rule

A definition of death is necessary because it is only after death that organs can be procured and transplanted, in keeping with the tenets of the fundamental bioethical precept of the Dead Donor Rule. It is at the moment of death that what are considered acceptable actions on a patient’s body change.48 The Dead Donor Rule contains two foundational postulates that govern the removal of organs for transplantation: (i) vital organs should only be taken from dead patients, and (ii) living patients should not be killed for, or by, organ procurement procedures.49 Therefore, in order to remove any vital organs, the patient must first be declared dead.

There have been two primary forms of determining when a patient can be declared dead – the brain death standard and the cardiopulmonary standard. Each of these definitions of death has spawned a separate donation archetype – donation after brain death and DCD. Under these two donation schemes, once a patient is “defined” as dead using their respective criteria, a donor’s organs can be removed. Donation after brain death is performed when a patient’s whole brain functions cease.50 DCD is performed when a patient has been declared dead according to cardiopulmonary medical criteria.51

48 Ozark & DeVita, supra note 26 at 170.
49 Ibid. at 172.
51 Ibid at 1.
Baker and Hargreaves suggest that DCD may be an attempt to breach the Dead Donor Rule.\(^\text{52}\) They note that under DCD protocols “managing death” is permitted with the objective of preserving organs, coupled with the fact that some anti-coagulants used to perfuse organs could hasten a donor’s death.\(^\text{53}\) Therefore, they argue that DCD could be “killing” the patient by prematurely removing their organs. This distinction turns on the moral difference between “killing” and “letting die”. In the case of DCD, Truog notes that patients are not killed; rather, they are determined to be dead prior to removing their vital organs (using the cardiac definition, because their heart and respiratory functions have ceased), thereby respecting the Dead Donor Rule.\(^\text{54}\) Truog and Miller, however, argue that the Dead Donor Rule should be entirely abandoned to avoid the appearance of “…gerrymandering the definition of death.”\(^\text{55}\)

F. Statutory Definitions of Death

The Harvard Committee concluded that no change in the law was required to shift to a brain death definition, because determination of death was a question of fact for medical doctors.\(^\text{56}\) Despite this, the President’s Council on Bioethics’ white paper, *Controversies in the Determination of Death*, ultimately led to the model *UDDA*, which has been adopted by most states nationwide.\(^\text{57}\) Section 1 of the *UDDA* provides that a person is dead when they have, “…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.”\(^\text{58}\) The *UDDA* recognizes death as determined by cardio-pulmonary criteria in the first part of the definition, thereby allowing for DCD. However, the *UDDA* also contains a caveat that, “…determination of death must be made in accordance with accepted medical standards.”\(^\text{59}\) Two decades after the adoption of the *UDDA*, this caveat resulted in the

\(^{52}\) Baker & Hargreaves, *supra* note 4 at 27.
\(^{53}\) A notion/argument that will be rejected later.
\(^{56}\) Harvard Committee, *supra* note 2 at 338.
\(^{57}\) President’s Council on Bioethics, *supra* note 50 at 5.
\(^{58}\) Ibid.
\(^{59}\) Ibid.
determination of death, at least for donation purposes, being made using brain death criteria as it remained the standard medical practice.\footnote{Ibid. at 6.}

This reliance on medical expertise is also reflected in the definition of death in the \textit{Trillium Gift of Life Network Act (TGLN Act)}. Section 7(1) provides that “[f]or the purpose of a post mortem transplant, the fact of death shall be determined by at least two physicians in accordance with accepted medical practice.”\footnote{\textit{Trillium Gift of Life Network Act}, R.S.O. 1990, c. H.20 [\textit{TGLN Act}]. The \textit{TGLN Act} replaced the \textit{Human Tissue Gift of Life Act}.}

\section*{III. DCD IN PRACTICE: THE ONTARIO EXPERIENCE}

In Ontario, the organization governing donation and transplantation is the Trillium Gift of Life Network (TGLN), established by the \textit{TGLN Act}, which legalizes organ transplantation in specific circumstances.\footnote{Most provinces and territories have similar legislation governing organ and tissue donation. See e.g. \textit{Human Tissue Gift Act}, R.S.B.C. 1996, c. 211, and; \textit{Human Tissue and Organ Donation Act}, R.S.A. 2000, c. H-14.5.} According to the TGLN, the need for organs exponentially outpaces the number of donors. In 2010, across Ontario there were 57 deceased donors and 80 living donors, but 1,523 patients are identified as awaiting organs in Ontario.\footnote{TGLN, “Donors”, online: TGLN <http://www.giftoflife.on.ca/page.cfm?id=3C963297-5F4C-479D-A635-AC8018D4FEC7>, and; TGLN, “Wait List by Organ”, online: TGLN <http://www.giftoflife.on.ca/page.cfm?id=58F02D0F-39DB-4BFE-A653-10E4F328C266>.} Clearly the current regime for organ donation is simply not resulting in enough donations to aid those in need. There have been many suggestions in the academic literature and in the popular media about ways to alter the system to increase donations. Ontario could switch to a presumed consent regime similar to the ones used in Spain and France, where residents are deemed to consent to organ donation after death unless they have opted out of the presumptive system.\footnote{Linda Wright, “Is Presumed Consent the Answer to Organ Shortages? No” (2007) 334 British Medical Journal 1089.} This contrasts with the current Ontario practice, which requires actual consent of donors or SDMs. While presumed consent systems have slightly increased organ donations in several countries, they have not come
close to eliminating waiting lists.\textsuperscript{65} Alternatively, options for out-of-country donors could be explored and potentially expanded. However, significant ethical and moral concerns surround “organ tourism”, such as publicized cases of exploitive and forced donations in India.\textsuperscript{66}

In Ontario, the TGLN has established a ten-step process for DCD, outlined in their DCD resource guide for health care professionals.\textsuperscript{67} The timing of the process is important not only to maximize organ viability but also to eliminate potential conflicts of interest and abide by ethical and legal guidelines. The first and most important steps of the process are: (i) making an end of life decision – often including withholding of life sustaining treatment, (ii) presentation of the DCD option, and (iii) obtaining consent for donation and any pre-mortem interventions.\textsuperscript{68} The TGLN DCD resource guide also provides that a physician not involved in the transplantation process will be responsible for declaring death. Surgical recovery of the organs can begin only after a five-minute absence of spontaneous respiration and pulse pressure. And, if a patient does not die within two hours after the removal of life sustaining treatment, they are to be transferred back to the ICU and should no longer be a DCD candidate, due to familial factors (such as stress on the family members) and operating room logistics.\textsuperscript{69}

A. End of Life Decisions
The first step in most DCD protocols requires the patient’s family, in consultation with the medical staff, to make a decision whether or not to withdraw life sustaining treatment, thus effectively letting the patient die. The patient’s family or SDM is often responsible for making the decision about withdrawing treatment because the patient is unconscious and thus decisionally incapable. In controlled cases, the only type of DCD recommended at this time by the Forum, a decision to withdraw care should and must be made without undue influence from the medical team. There is a possibility, generally theoretical, for transplant physicians to pressure families for donation with the prospect of procuring much needed organs clouding their

\textsuperscript{65} Ibid.
\textsuperscript{66} Dale Brazao & Noor Javed, “Dr. Horror Nabbed” \textit{The Toronto Star} (8 February 2008).
\textsuperscript{68} Ibid. at 7.
\textsuperscript{69} Ibid. at 10.
medical judgment (vis-à-vis the potential donor). Such a fear, albeit possibly unfounded and unlikely given the gravity of the probable illness, may deter patients or SDMs from seeking medical treatment when needed or lead them to refusing the consideration of organ donation altogether.

The public’s worry about hastening death has commentators such as Truog concerned about how the public and medical community would react to headlines such as, “doctors kill patients for their organs.” Ozark and DeVita echoed this sentiment by wondering what physicians might do in circumstances where the patient’s death did not occur “on schedule.” In 2007-2008, it was widely reported that a physician in California was charged with crimes related to hastening a patient’s death in order to procure his organs. The patient’s family had consented to the procedure one day before his organs were ultimately removed, but because the patient did not die within the thirty minutes allotted after life support had been withdrawn, it was alleged that in order to speed up the process the physician ordered excessive doses of harmful drugs. The physician was acquitted after two days of jury deliberations. A minor uproar in the medical community also occurred in 2008 when three neonate hearts were transplanted as part of a controlled DCD program, but only after waiting 66-75 seconds after withdrawal of life-sustaining treatment. When questioned why that particular time period was chosen, the response was that it was in the “…best interests of the recipient.” While cases such as these are rare, the mere fact that they do happen, and the widespread news coverage they garner, highlights the sensitivity of DCD issues and the need for physicians to have appropriate protocols in place when approaching families and conducting the procedures.

To avoid conflicts of interests, the Forum stipulates that no physician involved in the transplantation process or with any potential organ recipients should partake in the discussion about the patient’s end of life deci-

70 Truog, ”Brain Death,” supra note 54 at 279.
71 Ozark & DeVita, supra note 26 at 178.
74 Ibid.
This is not to suggest that such conflicts are inevitable or that physicians are often motivated purely by obtaining the most organs at whatever the cost to the donor. However, just as the justice system concerns itself with the ‘appearance of bias’ of judges, it is the appearance of bias or conflict on the part of physicians that colours the discussion. These conflicts can be avoided by adopting the recommendations of the Forum, such as the segregation of key duties. Organ procurement organizations should ensure that the patient care team in the ICU is responsible for any pre-mortem medications and are the ones responsible for discussions about any end of life decisions. The involvement of any transplant program participants could effectively ‘taint’ the discussion and raise the specter of bias and coercion. Similarly, any patient care team members who have any involvement or relationships with any potential transplant recipients should refrain from partaking in these discussions. This is clearly an added safeguard against the appearance of conflicts of interest because the patient care team has no direct involvement or interests in the transplantation process.

Organ procurement organizations, including the TGLN, have attempted to mitigate such conflicts of interest by requiring that the declaration of death be made by a physician not involved in the transplantation process. This segregation may not go far enough, however, as aside from the declaration of death, the patient care team and transplant teams are not required to be independent.

**B. Offering the DCD Option**

One of the major problems of current donation practices is that when families or SDMs have made a decision to withdraw life sustaining treatment, they are not presented with the option to donate because their hospital has not adopted a DCD protocol. In order to promulgate a DCD program of a substantial enough size to make a significant difference in Canada’s transplantation needs, the Forum recommended that the DCD option be presented to a patient’s family or SDM prior to the fact of death, but only after a decision to withdraw treatment has been made. Without this protection, presenting a family with the DCD option and then asking if they want to withdraw life sustaining treatment could easily be seen as an attempt to

75 Shemie et al., supra note 7 at 63.
76 Ibid.
77 Ibid. at 3.
coerce them to let their loved one die, even if it is for the altruistic purpose of benefiting someone else. Providing families the opportunity to make an independent decision about whether or not to withdraw treatment before discussing DCD avoids the appearance of a conflict. It also ensures that any regret the family may have about their choice cannot be redirected at the health care team. The U.S. Institute of Medicine (IOM) reports that following the presentation of the DCD option, families will ask questions such as whether their loved one is really dead, whether their loved one will feel any pain and what they as the family do next.\textsuperscript{78} The IOM recommends that during this time both patient care and donation personnel should be present to answer the families’ queries and to ensure that full and complete information is provided. It also recommended that if the hospital where the patient is located does not participate in a DCD program, the patient should be transferred to an appropriate facility if a decision to proceed with DCD is made, after obtaining informed consent for the move.\textsuperscript{79}

There are some academics who argue that DCD should only be offered to those patient’s families that request it. As noted above, the influence of health care members in discussions surrounding donation presents an opportunity for coercion and gives the appearance of a conflict of interest. The best solution to prevent coercion, Ozark and DeVita argue, is to prevent the health care team from approaching families at all about organ donation.\textsuperscript{80} This is supported by the IOM’s guidance in \textit{Non-Heart-Beating Organ Transplantation: Practice and Protocols}. It states that DCD should only be offered as an option if the family has expressed interest in donation.\textsuperscript{81} The IOM also reported that there was no evidence of denial of DCD after the option was presented. The problem with the IOM’s recommendations is that it only provides patient’s families or SDMs the option of DCD when interest in donation has been expressed. Such an approach overlooks those patients and families who would consider donation only if initially presented with the DCD option. It is highly doubtful that the majority of patients and their families are aware of the intricacies of Ontario’s organ donation program. At most, their understanding of organ donation is likely limited to the donation card they have the option of signing when they renew their drivers’ licenses. Therefore, it

\begin{flushright}
\textsuperscript{79} Ozark & DeVita, \textit{supra} note 26 at 179.
\textsuperscript{80} Ozark & DeVita, \textit{supra} note 26 at 179.
\textsuperscript{81} IOM, \textit{Practice and Protocols}, \textit{supra} note 10 at 28.
\end{flushright}
is important to give families as much information about the various donation options as possible, particularly given the potential increase in donated organs that could result.

C. Pharmacological Interventions & Comfort Care Measures
The timing of a patient’s cardiac arrest and accompanying life support interventions are important, as they greatly affect the viability of organs for transplantation. The greatest determinate of organ viability is warm ischemic time, which is the interval between the withdrawal of life sustaining treatments (often extubation) and the starting of cold perfusion of the organs. It is during this time that the blood supply to the organs is reduced and the tissue is gradually dying. There are several interventions that are undertaken to preserve and prepare the organs for transplantation. The best and most widely used method to preserve organ viability is cold perfusion, where the temperature of the organ to be transplanted is rapidly reduced. This often occurs through a process of pre-mortem cannulation through the use of catheters and occlusion balloons. The IOM has reported that catheters and cannulation themselves do not hasten death, but are nonetheless invasive and can be painful for the patient.

Pharmacological interventions are also undertaken which often include the use of anticoagulants such as Heparin and vasodilators such as Regitine (phentolamine). In its report, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, the IOM notes that the use of Heparin and phentolamines would not be part of the care of non-donating patients, but are part of the standard of care and best practices for donating patients. There are concerns that the use of these interventions may have a double effect – that is, a positive effect of preserving organ viability, but a negative effect of hastening death. In cases of DCD, participants who present with intercranial bleeding or blood volume deficiencies, anticoagulants and vasodilators are not indicated because of speculation that they could hasten death. The IOM recommends a case-by-case assessment of patients for the use of pharmacological interventions. Such an approach clearly provides

82 IOM, *Medical and Ethical Issues*, supra note 9 at 53.
83 Ibid. at 39.
84 Ibid. at 52.
85 Ibid.
a safety mechanism for bleeding patients by creating an exception, such that any chance of vasodilators or anti-coagulants hastening their death is removed. However, despite the concern, there have been no reported cases in which the introduction of pharmacological interventions associated with DCD has hastened a patient’s death.  

There are also concerns about what impact comfort care measures may have on a patient’s status. Comfort care measures make a patient’s condition and subsequent death more tolerable, as well as providing reassurance to family members. However, Ozark and DeVita argue that pre-mortem medication for pain prevention may in fact hasten death for the purpose of organ extraction, and thus may give rise to a potential conflict of interest. It is possible that a physician prescribing pain medication might do so to hasten the death of the patient in order to procure the organs, and not simply out of benevolence towards the patient or their family. Unlike other conflicts of interest that arise in the DCD context, this cannot be eliminated by separation of health care duties and will likely remain a small but nagging concern.

D. Organ Preservation by Cold Perfusion

While pharmacological interventions are the preferred tools to preserve viability, cold perfusion is necessary to ensure organ viability if the time until organ removal exceeds thirty to sixty minutes. Cold perfusion takes on particular significance in the circumstances of uncontrolled DCD. In cases of uncontrolled DCD the family is often not immediately present at the time the patient is brought into the ER, and thus they are not available to consent to the organ-preserving interventions or to the donation process generally. Even if the family is present when the patient is brought in, the reality of the patient’s imminent death, and the need to cope with this news, makes immediate decisions about donation options unlikely.

In such cases, immediate cold perfusion performed on a DCD candidate would at least leave the door open for donation, allowing the family the opportunity to weigh their options. On the flip side, failure to start perfusion immediately would irreparably jeopardize any use the organs may have for donation. It is estimated that the time frame for families to decide whether to donate in uncontrolled cases of DCD can be extended from a few minutes

87 IOM, Medical and Ethical Issues, supra note 9 at 52.
88 Ozark & DeVita, supra note 26 at 182.
to hours, provided cold perfusion interventions are started immediately.\(^89\) An additional non-medical benefit of prompt cannulation is that it allows the family an opportunity to stay with the patient prior to withdrawing life-sustaining treatment for up to sixty minutes following death.\(^90\) Reportedly, giving families more time to consider options surrounding donation significantly increases family approval for DCD.\(^91\) Youngner and Arnold support the notion that perfusing organs prior to consent provides families more time to decide whether or not to donate.\(^92\) This “buying time”, however, may all be for naught. As will be discussed below, the family likely does not have legal authority to consent to such interventions in the first place.

Doig and Rocker report that the Washington Hospital Centre has one of the most extensive DCD programs, with 30% of their donations coming from DCD patients.\(^93\) However, they theorize that this large percentage of donations obtained from DCD might reflect the hospital’s practice of permitting in-situ preservation of uncontrolled DCD donor patients without their direct consent. Thus, the candidates for DCD are all treated as potential donors, and the viability of their organs maintained until the family is contacted and a decision is made. This statistic might subtly but optimistically highlight the fact that families are generally receptive to DCD when presented with the option. If the in-situ preservations were not performed prior to receiving consent, then the patients would never have been donors at all. The extended time the preservations allowed the families gave them the opportunity to consider DCD, and they responded positively. Therefore, prompt cannulation could result in an increased organ supply.

A major hurdle, however, is that it might represent the criminal offence of interference with a dead body, as consent was not first obtained.\(^94\) In the case of uncontrolled DCD, some jurisdictions explicitly permit preservation procedures while families are contacted.\(^95\) In the absence of specific legislation in Canada, the Forum recommended that organ-sustaining interventions should only proceed with express consent or intent.\(^96\) This position is

---

89 Ibid. at 186-187.
90 IOM, Practice and Protocols, supra note 10 at 51.
91 Shemie et al., supra note 7 at 73.
92 Youngner & Arnold, supra note 15 at 74.
93 Doig & Rocker, supra note 17 at 1071.
94 Criminal Code, R.S.C. 1985, c. C-46, s. 182.
95 IOM, Practice and Protocols, supra note 10 at 52.
96 Shemie et al., supra note 7 at 35.
similar to that of the Netherlands, where consent is required before catheterization is undertaken.  

**IV. LEGAL AND ETHICAL ISSUES OF CONSENT**

**A. Consent to the Donation Procedure**

Generally, a person can consent to have their organs donated upon their death provided they are at least sixteen years of age, have reduced their wishes to writing or made them orally and that this was witnessed by at least two other people. The individual’s consent is binding unless there is reason to believe that it has subsequently been withdrawn. Therefore, if the physicians are presented with a patient who has a validly signed donation card or has expressed their wishes to their family members, there is no legal reason to seek consent from the family, although in practice they often do. In the United States, the Uniform Anatomical Gift Act gives explicit priority to a donor’s express intent such that it cannot be revoked by others. Donations and interventions without consent may bring criminal liability under the Criminal Code, which could underpin such charges as assault (provided all the elements of the offence are proved). Similarly, civil liability may be founded in the tort of battery.

The use of organ donation cards by the TGLN presents difficulties. Participants in the TGLN sign an organ donor card to opt-in to Ontario’s donation program, thereby consenting to the post-mortem removal of their organs. The primary issue is that if the donation card signals a donor’s prior wishes, as per section 4(1)(a) of the TGLN Act, then the consent is to be used “after the person’s death.” But the question remains, what definition of death and what, if any, organ preservation procedures are the public beholden to, by signing the card? Richards and Rogers observe that in the Australian opt-in system, which is similar to Ontario’s, “consent…may only be assumed for organ donations in situations familiar to the public.” Since DCD is a rela-

---

97 Koostra et al., supra note 18 at 96.
98 TGLN Act, supra note 61 s. 4(1).
99 Ibid., s. 4(3).
100 Rady, Verheidje & McGregor, supra note 6 at 328.
101 Bernadette Richards & Wendy Rogers, “Organ Donation after Cardiac Death: Legal and Ethical Justifications for Antemortem Interventions” (2007) 187 Medical Journal of Australia 168 at 168. It should be noted that the TGLN Act,
tively new (or newly revisited) phenomenon in the modern donation world, it is fair to at least consider the possibility that the public is not consenting to DCD when signing the donation cards, especially given the invasive interventions that may accompany DCD. Thus, any actions by physicians ostensibly in accordance with a patient’s card-based wishes, may be inappropriate and not in accordance with the TGLN Act or the Health Care Consent Act (HCCA).\textsuperscript{102} This uncertainty over what the cards themselves represent in terms of definitions raises serious issues about moving forward with DCD without further clarification.

B. Consent to Interventions Ancillary to the Donation Procedure

\textit{(i) The Statutory Framework}
Performing cannulation and other invasive procedures or administering medications to patients without consent raises serious ethical and legal issues. A physician’s duty of beneficence is anchored in their duty to provide therapeutic benefits to their patient. However, these interventions do not provide any medical or therapeutic benefit to the potential donor. Both at common law and pursuant to the \textit{HCCA} there is to be no treatment without consent, and health care practitioners must take reasonable steps to ensure that treatment is not administered without the patient’s consent. Section 2 of the \textit{HCCA} defines treatment broadly as “...anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, and includes a course of treatment, plan of treatment or community treatment plan.”\textsuperscript{103} Combing through this definition it is difficult to be certain what each component encompasses. Procedures maintaining organ viability for the purpose of donation do not easily fit into any of them. Therefore, if there is no treatment without consent, then the \textit{HCCA} does not appear to apply in circumstances where the procedure is not a treatment.

In the event that interventions aimed at maintaining organ viability are considered “treatments” under the \textit{HCCA}, the \textit{HCCA} may have limited application to such interventions when SDMs are involved. Section 6.3 of the \textit{HCCA} provides that the Act, “…does not affect the law relating to giving or refusing consent on another person’s behalf to...the removal of regenerative

\textsuperscript{102} \textit{Health Care Consent Act, 1996, S.O. 1996, c. 2, Sch. A, s. 10(1) [HCCA].}
\textsuperscript{103} \textit{Ibid., s. 2.}
or non-regenerative tissue for implantation in another person’s body.”

Thus, if SDMs are involved in providing or refusing consent for transplantations of regenerative or non-regenerative tissues (including organs) then the HCCA does not apply. Instead, when SDMs are involved, the procedures are governed by the TGLN Act.

Another question that arises in interpreting section 6.3 is whether or not the interventions aimed at maintaining organ viability can be classified as “removal of tissue”. Clearly the interventions themselves do not involve the removal of tissues, but they may be covered under the general procedure as necessarily incidental to the removal of tissue. It is unclear from the wording of section 6.3 whether it applies to ancillary procedures or whether it is restricted to the primary procedure. In the latter case, both the HCCA and the TGLN Act would seem to apply to transplantations. The TGLN Act would govern the primary procedure after death and the HCCA would apply to procedures such as patient preparation. However, it is doubtful that the legislature intended a separate statute to govern different aspects of what is arguably the same procedure, which may be evidenced by the exclusionary rule embodied in section 6.3 of the HCCA. If neither the HCCA nor the TGLN Act is applicable to interventions aimed at maintaining organ viability all that remains is the common law.

Richards & Rogers, among others, argue that implicit in consent to a general transplantation procedure is consent to all its constituent parts and sub-procedures which facilitate the whole. They believe it is normal to expect that a potential donor wants to donate organs that function as well as possible. They contend that it is reasonable to conclude that when consenting to the general donation, the donor is also consenting to all necessary interventions to make the donation possible. While this line of argument is compelling, it fails to recognize the aforementioned concern that many members of the public may not be aware of the extent to which interventions may be necessary for organ preservation. Thus, their consent to the general DCD procedure may not be fully informed, because of a lack of disclosure surrounding the nature of the treatment.

104 Ibid., s. 6.3.
105 Richards & Rogers, supra note 101 at 169.
106 As governed by section 11(3) of the HCCA, supra note 102, and common law.
(ii) The Common Law

It is unclear whether the TGLN Act applies to ancillary procedures to DCD, such as pre-mortem interventions. Section 4(3) sets out what authority consent to post-mortem donation gives transplant physicians: “[u]pon the death of a person who has given a consent under this section, the consent is binding and is full authority for the use of the body or the removal and use of the specified part or parts for the purpose specified.”\(^{107}\) The key factor is that the authority granted under this subsection only applies “upon death” of the donor. Thus, if the donor has not yet died, as is the case with pre-mortem interventions (because the patient is often still on life support until moments before the transplantation), then the TGLN Act by its own terms would not apply. The common law would also govern if the procedures were not considered to be exempt from the HCCA pursuant to section 6.3, because it is doubtful that the interventions in question would be considered “treatments”. This is evidenced by section 8(2) of the HCCA which provides that, “…this Part [consent to treatment] does not affect the law relating to giving or refusing consent to anything not included in the definition of “treatment” in subsection 2(1).”\(^ {108}\)

The common law in the area of consent is fairly straightforward. It holds that, generally, consent is required before any procedure is performed on the patient. This is founded in the right to bodily integrity. The Supreme Court of Canada held in Ciarlariello v. Schacter that every patient has a right to bodily integrity that covers, “…the right to determine what medical procedures will be accepted and the extent to which they will be accepted. Everyone has the right to decide what is to be done to one’s own body. This includes the right to be free from medical treatment to which the individual does not consent.”\(^ {109}\) Performing any procedure without consent can give rise to civil and criminal liability.\(^ {110}\) Consent to a general procedure generally includes sub-procedures that are necessary or usual in relation to the procedure to which the consent relates.\(^ {111}\) This coalesces with the general proposition

---

107 TGLN Act, supra note 61, s. 4(3).
108 HCCA, supra note 102, s. 8(2).
110 Ibid.
that consent must be referable to the proposed treatment. However, these cases have typically dealt with procedures that could be considered a therapeutic benefit to the consenting patient (here, the donor).

(iii) Timing Issues

The Forum distinguished between consent that may be required before death and consent that may be required after death. For example, prior to the fact of death, any interventions undertaken to facilitate donation and organ viability require “…specific and informed consent…for each intervention.”

Post-death interventions, however, only require general consent, i.e. to the donation. The two are differentiated because of different governing laws and different concerns for the donor, with the former directly impacting the patient’s physical state via pain and intrusiveness levels. In regards to the former, for example oxygen perfusion, the common law likely governs and requires specific and informed consent. If the specific interventions were included in the definition of “treatment” in the HCCA, and not exempt under section 6.3, consent would be required to comply with the informed consent requirements of section 11(3) of the HCCA. For those ancillary actions after death, section 4(1) of the TGLN Act only requires a patient’s general consent for the use of their body after death and leaves the context broad enough to encompass any associated procedures performed post-mortem.

If perfusion is performed prior to obtaining consent, Youngner and Arnold worry that if a patient’s family ultimately refuses to consent to donation that they may not be told the perfusion procedure was performed. Their worry finds grounding in section 11(1) of the HCCA which provides that consent must not be obtained through misrepresentation and fraud. It may be considered a misrepresentation to ask families for consent to the interventions when they have already been performed.

112 Nelson, ibid.
113 Shemie et al., supra note 7 at 33.
115 TGLN Act, supra note 61, s. 4(1).
116 Youngner & Arnold, supra note 15 at 74.
117 HCCA, supra note 102, s. 11(1).
C. Consent of SDMs

(i) Legislative Void
Even if consent were obtained, under common law or statute, the question remains whether consenting to medically non-beneficial actions is permitted, either by the donor themselves or by SDMs. SDMs are necessary in almost all DCD cases because first person consent from the patient is extremely rare due to the nature of the illness which renders the patients incapacitated. In R. v. Jobidon, the Supreme Court of Canada held that a person cannot consent to serious non-trivial bodily harm. However, that was a case of fist fighting and not a decision to donate organs to help others, so it is doubtful whether that ratio would apply in the case of pre-mortem interventions.

If, as discussed, neither the TGLN Act nor HCCA apply to pre-mortem interventions, the common law governs the role of SDMs (in consenting to such actions). At common law, there are no SDMs for incapacitated adults save for court-appointed guardians or the court itself. Thus, family members, other than parents of minor children, have no legal authority to consent to treatment for others at common law. Under the common law SDMs are not legally permitted to consent to DCD interventions on a patient’s behalf. In the unlikely scenario that either the HCCA or TGLN Act apply, they would override the common law, thus permitting consent by SDMs. With that said, there is an unfortunate lack of congruency between the HCCA and the TGLN Act in ranking possible SDMs who are permitted to consent to pre-mortem interventions if the patient is incapable. Section 5(1) of the TGLN Act provides first ranking to the patient’s spouse whereas the first rank under section 20(1) of the HCCA is the patient’s guardian followed by the patient’s attorney for personal care, neither of whom are mentioned in the TGLN Act. In addition the HCCA ranks a patient’s partner equally with their spouse, but there is no mention of “partner” in the TGLN Act. Under section 20(9) of the HCCA, partner is defined as “either of two persons who have lived together for at least one year and have a close personal relationship that is of primary

118 New York State Taskforce on Life & the Law, supra note 1 at 9.
importance in both persons’ lives.” Thus, if the TGLN Act governs in situations where an individual fit the definition of partner under the HCCA, they would have no standing as an SDM.

**(ii) The “Best Interests” Standard**

Once the identification of the SDMs is determined, the question remains as to what principles and sources they are permitted to draw on when making their decision about the interventions. Section 5(2) of the TGLN Act stipulates that SDMs may give consent in the absence of wishes expressed by the donor patient. Section 5(3) of the TGLN Act provides that consent shall not be given by SDMs if they had reason to believe the patient would have objected. Thus, there are no requirements that SDMs consider anything other than his/her own opinion in making this determination, save for the “reason to believe otherwise” exception. Therefore, even if the patient did not wish to donate, if they did not express it in the form of prior wishes, the SDM has full authority to provide consent to the donation procedure. This is contrasted with section 21 of the HCCA which requires the SDM to decide in the “best interests” of the patient when prior capable wishes are unknown or inapplicable.

The “best interests” standard is of particular significance due to the fact that while the patient may have previously consented to organ donation, he/she has not specifically consented to those invasive interventions that often accompany DCD. If the HCCA applies and there are no prior wishes, then for the SDM to consent, the interventions would have to be considered as some sort of therapeutic benefit, or compliance with prior wishes, under section 21. However, as has already been noted, the therapeutic nature of these procedures vis-à-vis the donor is extremely doubtful at best. Thus, in order for DCD to proceed, the two must be aligned. The general consensus in the literature is that by performing the interventions necessary to ensure a successful donation, the patient’s interests and wishes to donate are honoured, and such wish-realization constitutes a net benefit to the patient. However, the possibility remains that the patient wanted to donate but not at all costs.

Furthermore, “best interests” factors as described in section 21(2)(c) of the HCCA would seem to tilt in favour of finding that such interventions are not in the patient’s best interests. After all, the interventions will not

---

121 HCCA, supra note 102, s. 20(9).
improve the patient’s condition, or prevent it from deteriorating, and, in fact, might cause it to deteriorate. The patient will receive no medical benefit from the treatment compared to the risks of harm that the treatment represents. Some may argue that it is in the patient’s best interests that one’s wishes are followed and that compliance with a patient’s beliefs and values is itself a benefit. While true, it is doubtful that such a benefit was specifically intended to be captured under section 21(2)(c) of the HCCA, where the purpose is in part to weigh the medical benefits and risks. Unfortunately, it seems logical that the “best interests” and SDM analysis above is moot given the fact that neither the HCCA nor TGLN Act appear to apply to DCD pre-mortem invasive interventions. Instead the common law, and its limited role for SDMs, applies. Thus, it is apparent that interventions that accompany DCD cannot legally be consented to by SDMs as they have no authority to do so at common law. They can only be consented to by patients directly, if at all, either at the time, or by advance directive.

V. CONCLUSION

While the statistical ability of DCD to alleviate the current organ shortage in Canada is unquestioned, it is only a small step towards complete organ-donor parity. This paper has demonstrated numerous ethical and legal difficulties with DCD. The legal ability of physicians to unilaterally, and perhaps too secretly, alter the definition of death and develop new donation protocols has been questioned and criticized by numerous commentators. The Pittsburgh Protocol in the U.S. was the first to develop a set protocol for DCD and several organ procurement organizations since have emulated their program. However, concerns and discrepancies persist among such organizations regarding the length of pulselessness required before death is pronounced. Protocols and laws also differ on the use and definition of “irreversibility”, an issue far beyond the scope of this paper. While many commentators express great concern about conflicts of interest among health care professionals, the evidence shows that this is over-stated and virtually all protocols have policies in place that protect against such problems.

Any required pre-mortem interventions also raise serious doubts about the legality of consent. Reliance on donor cards as evidence of prior wishes or consent has been shown to be questionable given the lack of public understanding and acceptance of DCD. In addition, the legislative void created by separate health care consent and donation statutes has led to questions concerning SDMs’ ability to consent to the interventions mentioned above, due to prohibition on such proxies in the common law. In
the event that those statutory provisions are interpreted differently by the courts, the “best interests” standard appears to only be applicable where the donor has expressed a desire to consent, and thus a SDM agreeing to pre-mortem interventions can only do so under those circumstances. It is clear that a new legislative framework is required to overcome the deficiencies in consent before proceeding any further with DCD. At the end of the day the uncertainty surrounding the legality of many aspects of DCD, coupled with the concerns about ethical implications and the lack of public awareness of DCD, militates in favour of limited, if not halted, further use of DCD in Canada.