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SPECIAL ARTICLE

Eligibility for organ donation: a medico-legal perspective on defining and determining death

L'admissibilité au don d'organe: définir et déterminer le décès – une perspective médico-légale

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Abstract

Purpose *In the context of post-mortem organ donation, there is an obvious need for certainty regarding the legal definition and determination of death, as individuals must be legally pronounced dead before organs may be procured for donation. Surprisingly then, the legal situation in Canada with regard to the definition and determination of death is uncertain. The purpose of this review is to provide anesthesiologists and critical care specialists with a medico-legal perspective regarding the definition and determination of death (particularly as it relates to non-heart-beating donor protocols) and to contribute to ongoing improvement in policies, protocols, and practices in this area.*

Principal findings *The status quo with regard to the current legal definition of death is presented as well as the criteria for determining if and when death has occurred. A number of important problems with the status quo are described, followed by a series of recommendations to address these problems.*

Conclusions *The legal deficiencies regarding the definition and determination of death in Canada may place health care providers at risk of civil or criminal liability, discourage potential organ donation, and frustrate the wishes of some individuals to donate their organs. The definition and criteria for the determination of death should be clearly set out in legislation. In addition, the current use of non-heart-beating donor protocols in Canada will remain inconsistent with Canadian law until more persuasive evidence on the potential return of cardiac function after cardiac arrest is gathered and made publicly available or until a concrete proposal to abandon the dead donor rule and amend Canadian law is adopted following a process of public debate and intense multidisciplinary review.*

Résumé

Objectif *Dans le contexte d'un don d'organe post-mortem, il est évident qu'il est nécessaire de ne laisser la place à aucun doute quant à la définition et à la détermination du décès; en effet, un individu doit être déclaré légalement mort avant que ses organes ne puissent être utilisés pour un don. Dès lors, il est surprenant de noter que la situation légale au Canada concernant la définition et la détermination du décès est floue. L'objectif de ce compte-rendu est de proposer aux anesthésiologistes et intensivistes une perspective médico-légale quant à la définition et la détermination du décès (en particulier en ce qui touche aux protocoles de donneurs à cœur non-battant) et d'apporter notre contribution aux progrès continus en matière de politiques, de protocoles et de pratiques dans ce domaine.*

Constatations principales *Nous présentons le statu quo concernant la définition légale actuelle du décès ainsi que les critères utilisés pour déterminer si et quand le décès est survenu. Plusieurs problèmes importants concernant le statu quo sont décrits; nous proposons ensuite une série de recommandations pour résoudre ces problèmes.*

Conclusion *Les lacunes légales quant à la définition et la détermination du décès au Canada pourraient mettre les*

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professionnels de la santé à risque de poursuites en responsabilité civile ou criminelle, décourager les dons d'organe potentiels, et frustrer le souhait de certaines personnes de faire don de leurs organes. La définition et les critères employés pour déterminer le décès devraient être clairement énoncés dans la loi. En outre, l'utilisation actuelle de protocoles de donneurs à cœur non-battant au Canada demeurera en contradiction avec la loi canadienne jusqu'à ce que davantage de données probantes convaincantes concernant le retour potentiel de la fonction cardiaque après un arrêt cardiaque soient récoltées ou rendues publiques, ou jusqu'à ce qu'une proposition concrète d'abandonner la règle du donneur décédé et d'amender la loi canadienne soit adoptée après un processus incluant un débat public et une révision pluridisciplinaire approfondie.

Introduction

The legal nature of death and its relation to post-mortem organ transplantation practices is a highly charged and complex subject. This work explores how death is defined in the Canadian legal context and describes limitations and uncertainties embedded in prevailing legal criteria for determining when death has occurred. Problematic features related to the interaction of the legal nature of death and post-mortem organ transplantation procedures are thus revealed. Ameliorative suggestions for law reform are provided, and the implications of these reforms for organ donation practices in Canada are identified.

The importance of having a clear legal framework dealing with the definition and determination of death is made stark in the context of post-mortem organ donation. In this context, Canadian law holds that an individual must be pronounced dead before organs may be procured for donation.[A] However, the confusing state of current Canadian law with respect to the definition and determination of death places health care providers in a situation where they may face civil or criminal liability for procuring organs prematurely, even in cases where they are following established protocols. Some measure of good faith immunity is provided to health care professionals under current organ donation legislation,[B] but this immunity is inoperative at the federal level and, therefore, offers no protection from criminal prosecution.[C] In other words, were a court to find the procurement of organs a legal cause of death, provincial/territorial organ donation legislation could provide no protection against a federal charge of homicide.[D]

The confusing state of Canadian law also has the potential to place donors in a perturbing situation. On the one hand, a donor's organs may be procured prematurely. On the other, a donor's wishes to donate may be frustrated as health care providers delay the pronouncement of death and fail to procure the organs before they are irreparably harmed during a prolonged period of warm ischemia. The recent development of non-heart-beating donor (NHBD) protocols[E] in Canada is aimed at avoiding the frustration problem, but it introduces the possibility of procurement

[A] *Robertson AJ*. The Dead Donor Rule. Hastings Cen. Rep 1999; 29: 6–14.

[B] See e.g., *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215, s. 10.

[C] Constitutionally, Provincial Statutes have no power to override federal liability. *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5.

[D] The *Criminal Code* states that "[a] person commits homicide when, directly or indirectly, by any means, he causes the death of a human being". To be found guilty of murder/manslaughter a person must commit a culpable homicide (non-culpable homicide is not an offence), the definition of which includes causing death "by means of an unlawful act". *Criminal Code*, R.S.C., 1985, c. 46, s. 22 (5)(a). Hence, the removal of a donor's organs prior to the donor's death, even if done inadvertently and in good faith by a physician, may be considered an unlawful act sufficient to sustain a homicide conviction.

[E] Non-heart-beating organ donation protocols rely on a cardiac determination of death (as contrasted with neurological determination of death) where, following withdrawal of life support (a decision made prior to and independent from the decision to donate organs) the patient's death is declared after a period of time has elapsed from asystole (inability to produce a pulse or blood flow). The time period varies depending on the jurisdiction but is generally in the 2–5 min range (with 10 and 20 min also used). After this period of time has elapsed, death is declared and the procurement of organs begins immediately.

The Canadian Council for Organ and Tissue Donation and Transplantation (CCDT) has endorsed the division of NHBD protocols into two categories: (1) controlled donation after cardiocirculatory death (DCD) and (2) uncontrolled DCD. Controlled DCD refers to situations where donation will occur in circumstances where the death of the donor is anticipated and will take place in an ICU or other special care hospital unit (i.e., the patient is suffering from a non-recoverable injury or illness, she is dependent on life-sustaining therapy, she has expressed a contemporaneous or prior-capable wish to have life-sustaining therapy withdrawn, and medical opinion supports a prognosis of imminent death upon withdrawal of therapy). In contrast, uncontrolled DCD refers to situations where donation is considered after death has occurred, but where it was not anticipated (and where there has been a decision to terminate or not engage in resuscitation). The CCDT has recommended that Canadian centers proceed first with controlled DCD and that they not implement uncontrolled DCD protocols until "controlled DCD programs are well established with demonstrable quality assurance". See, *Shemie SD, Doig C, Sickens B, et al.* Severe brain injury to neurological determination of death: Canadian forum recommendations. CMAJ 2006; 174: S1–S12 (recommendation 9.2).

before brain death (whether this is "premature" is, of course, the subject of debate).[F]

Ongoing legal uncertainty surrounding the definition and determination of death may also be undermining efforts to increase the number of Canadian donors. A 2006 survey revealed that 20% of Canadians felt it was either certain (7%) or probably true (13%) that their organs would be removed before they were actually dead. Furthermore, only 43% of Canadians felt "certain" that their organs would not be removed until after they were dead, and 35% of Canadians believed that this was "probably true".[G]

The backdrop to the present analysis is a disordered legal framework that has contributed to a climate of general uncertainty. This uncertainty leaves health care providers vulnerable to legal sanctions for doing their jobs and leaves potential donors vulnerable to premature procurement of their organs or to frustration of their desire to donate. It may also be contributing to the severe shortage of organ donors in Canadian society.[H] Legislative reform should be considered to address legal uncertainties surrounding the use of NHBD protocols. This is directly relevant to anesthesiologists and critical care specialists because the number of NHBD donations in Canada is rising. Consequently, increased numbers of practitioners will likely be asked to participate in these protocols. With respect to these practitioners, the aim of this paper is twofold: (1) to provide a detailed understanding of the medico-legal situation surrounding NHBD protocols, and (2) to formulate recommendations to improve policies, protocols, and practices in this area.

The legal definition and determination of death in Canada

Case law

There has only been one reported case in Canada in which the definition and determination of death has come before the courts in the context of organ donation. In *R. vs Kitching*,[I] an assault outside a bar led to charges of manslaughter against two accused. The victim was taken to hospital shortly after being assaulted and, since he had no respiration, pulse, or cardiac function, the victim was given artificial resuscitation and his breathing and cardiac function were restored. The victim was able to breathe spontaneously but insufficiently and so was placed on a ventilator. Some hours later, he was found by one physician to have suffered total brain death. The next day, a different physician diagnosed a total absence of brain stem function. The victim was no longer able to breathe spontaneously, but he was not declared dead. The victim subsequently went into cardiac arrest and physicians intervened in order to preserve his organs for donation. Following organ procurement, mechanical ventilation was withdrawn. Thirteen minutes after the removal of cardiac life support, the victim's heart stopped beating and his death was declared.

Both accused were found guilty of manslaughter. At trial, a great deal of evidence was put forward in relation to the criteria for the definition and determination of death (as defence counsel sought to persuade the court that the legal cause of the victim's death was the removal of life support and not the actions of the defendants). However, the case turned entirely on other issues. On appeal to the Manitoba Court of Appeal, the majority of the Court did not speak to the issue of the definition or determination of death (again, the case was decided on other grounds). However, writing for himself, Justice O'Sullivan took up the issue of the medical evidence and canvassed various approaches to defining and determining death. He acknowledged the traditional role of cardiac function in medicine and law (see footnote I) but also noted the more recent development of the Harvard criteria.[1] He concluded that "these questions [about the definition and determination of death] are important and they may have to be considered by the courts some day. In my opinion, however, they were not properly before the court in the case before us" (see footnote I). In the end, despite first appearances, this case provides no authority in relation to the issues before us in this paper.

There are five other cases in which the definition and determination of death have come before the court, albeit in contexts other than organ donation.

In the 1988 murder case, *R. vs Green*, the British Columbia Supreme Court embraced the irreversible cessation of cardiopulmonary function as the criterion of death (characterizing this as the "traditional approach") and refused to adopt brain death for the purposes of determining death in the criminal law context. The Court held that, as a matter of law, the victim "was alive so long as

[F] It is important to note that the discussion and argument put forward in this paper do not relate to *inter vivos* organ donation. The legal rules that apply to pre-mortem organ procurement are distinct from those applying to post-mortem organ procurement. See e.g., *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215. Part I.

[G] Environics Research Group. Public Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation After Cardiac Death (Final Report) (Toronto: Environics Research Group Limited, April 2006) at 25 [unpublished].

[H] Recent Canadian Institute for Health Information statistics on this topic show that in 2007 there were 4,195 patients waiting for organs in Canada. Online: http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=reports_corrstats2007c_e.

[I] *R. vs Kitching* (1976), 32 C.C.C. 2d 159 (Man. C.A.), leave to appeal refused (1977), 32 C.C.C. (2d) 159n (S.C.C.).

any of his vital organs—which would include his heart—continued to operate".[J] However, it is important to note here that the court stated:

> The suggestion that brain death or the irreversible cessation of brain function be the legal standard for determining when death occurs may be suitable in the medical context and even in the civil law context, but in my view it is a completely impractical standard to apply in the criminal law… On the face of it I see no reason why the same legal definition of death must be applied in both a civil and criminal context. Indeed there are good reasons why the same criteria should not apply. (see footnote J)

It is important to note here that the court saw organ donation issues as resting in "the medical context and even the civil law context", and so its rejection of the use of brain death in the criminal law context should be read narrowly as applying to the criminal law context of "violent crime" that "endangers the life and safety of others" (in this case, the question was whether a person who shot two bullets into the head of a man immediately after someone else had shot one bullet into his head caused the man's death). That is, the rejection might not apply to criminal charges in the context of organ procurement.

In the other four cases,[K] the concept of brain death was adopted (in three, loss of total brain function and, in one, loss of brain stem function). The most recent case, in 2005, contained a lengthy discussion of the definition and determination of brain death. Justice Bureau of the Quebec Superior Court offered the following strong statement:

> Over the years, a consensus has developed in both legal and medical professions regarding the definition of death. It is now clearly established that death is determined on the basis of brain death. There no longer seem to be any fundamental differences of opinion on this point.[L]

Justice Bureau acknowledged that there are differences of opinion with respect to how to define brain death but concluded that total brain death is required for death:

> Of course, everyone now recognizes that brain death is equivalent to a person's death, but it must be total brain death, namely, the cessation of all cerebral activities including those of the brain stem, and not only those of the cerebral cortex. (see footnote L)
>
> It was at that moment that all his brain functions, including those of the brain stem, ceased irreversibly and he died. (see footnote L)

While Justice Bureau's certainty is not backed up with authorities for his conclusions about universal acceptance of brain death, it is certainly reasonable to conclude, at least on the basis of the cases that are available, that death in the context of organ donation may well be considered by the courts to be determined by the absence of all brain functions. However, given that no courts have addressed the issue of the definition and determination of death for the purposes of organ procurement and, given the low level of the courts that have spoken even indirectly on this issue, no stronger conclusion than this can be drawn from the case law.

Statute

Given the importance of the issue, it is surprising that there is no federal statutory definition of death. Provincially, Prince Edward Island and Manitoba have made some efforts in this regard. Section 1(b) of the P.E.I. *Human Tissue Donation Act* states that "death includes brain death as determined by generally accepted medical criteria".[M] Section 2 of the Manitoba *Vital Statistics Act* reads as follows: "For all purposes within the legislative competence of the Legislature of Manitoba the death of a person takes place at the time at which irreversible cessation of all that person's brain function occurs."[N] In Manitoba, the *Human Tissue Gift Act* directly references the *Vital Statistics Act*.[O]

In New Brunswick, s. 7(1) of the *Human Tissue Gift Act* reads as follows:

[J] *R. vs Green* (1988), 43 C.C.C. (3d) 413 (B.C. S.C.).

[K] In chronological order: (1) *Kerr vs B.C. Motorist Insurance* [1972] 6 W.W.R. 400, 30 D.L.R. (3d) 443 (total brain death); (2) *Johannisse vs Johannisse Estate* [1985] O.J. No. 1273 (total brain death); (3) *London Health Science vs K. (R.) (Litigation Guardian of)* [1997] O.J. No. 4128, 152 D.L.R. (4th) 724 (brain stem death); (4) *Leclerc (Succession) vs Turmel* [2005] R.J.Q. 1165, 2005 Carswell Que 790 (total brain death).

[L] *Leclerc (Succession) vs Turmel* [2005] R.J.Q. 1165, 2005 Carswell Que 790.

[M] *Human Tissue Donation Act*, S.P.E.I. 1992, c. 34, s. 1(b). This definition is not a true definition in that it does not articulate what death means but instead what death includes. This definition is also contained in s. 1 of The Uniform Human Tissue Donation Act. Uniform Law Conference of Canada—Uniform Statutes—Human Tissue Donation Act, April 1990. Available from: http://www.ulcc.ca/en/us/index.cfm?sec=1&sub=1h1. The Uniform Law Conference of Canada develops uniform or model acts at the request of its constituent jurisdictions, namely the federal, provincial, and territorial governments. These governments appoint delegates to the Conference, such as government policy lawyers, private lawyers, or law reformers. The Conference's current uniform *Human Tissue Donation Act* of 1989 is one of many uniform statutes that the Conference has adopted and recommended for government enactment. The current version has been made into law only in Prince Edward Island.

[N] *The Vital Statistics Act*, R.S.M. 1987, c. V60, s. 2.

[O] *The Human Tissue Gift Act*, S.M. 1987–1988, c. 39, s. 8(1).

> For the purposes of post-mortem removal of a human body part or parts for implantation in a living human body, the fact of death must be determined in accordance with accepted medical practice by
>
> (a) at least 2 medical practitioners, when the fact of death is determined in accordance with neurological criteria, or
> (b) one medical practitioner, when the fact of death is determined by other criteria.[P]

In Quebec, the statutes are silent, and this silence, according to the Ministry of Justice, was deliberate: "It was not deemed appropriate to provide a definition of death [in the *Civil Code of Quebec*], since death is a fact whose assessment is based on criteria other than legal. Furthermore, such a definition could only be provisional given the developments in science."[Q]

In the Northwest Territories and Nunavut, organ donation legislation is silent on the criteria for the determination of death without any explanation of the silence. In the remaining provinces and territory (Newfoundland, Nova Scotia, Ontario, Saskatchewan, Alberta, British Columbia, and the Yukon), there exist no explicit legislative criteria for the determination of death. However, organ donation legislation in these jurisdictions contains the following provision: "For the purposes of a post-mortem transplant, the fact of death shall be determined by at least two physicians in accordance with accepted medical practice."[R] In no case does the relevant legislation define "accepted medical practice". We must therefore turn to other sources for insight into the meaning of "accepted medical practice" and, thereby, the statutory basis for determining death (in Newfoundland, Nova Scotia, New Brunswick, Ontario, Saskatchewan, Alberta, British Columbia, and the Yukon).

In 1968, an Ad Hoc Committee from Harvard Medical School published a seminal report on the neurological criteria for determining brain death.[1] As summarized by J. Menikoff:

> That report concluded that the traditional use of pulmonary and respiratory criteria for determining death has always served – whether or not our ancestors truly understood this – merely as a surrogate for determining the status of a person's brain, the function of which could not directly be measured… Recognizing that the usual criteria would no longer work for a person whose breathing was maintained by a machine, the Committee provided specific criteria for measuring lack of brain function in a person so to declare that person dead. These were the scientific criteria that would ultimately evolve into the tests used in declaring a person "brain dead".[2]

Since the publication of the Harvard Report, determining death according to neurological function (neurological determination of death, NDD) has been widely accepted in Canada[3] and in other countries. Originally, the implementation of the Harvard NDD criteria varied across Canada, because hospitals and regions were responsible for setting specific NDD standards and practices.[4] In response to the heterogeneous practice standards, the Canadian Congress Committee on Brain Death created uniform guidelines in 1988[5]; the Canadian Neurological Care Group later updated these guidelines in 1999.[6] However, in spite of their best efforts, these initiatives failed to produce uniformity in practice across the country.

In 2003, the Canadian Council on Donation and Transplantation (CCDT) sponsored a national multidisciplinary forum, "Severe Brain Injury to Neurological Determination of Death", which developed new recommendations for harmonizing practice around NDD. It recommended that NDD "be defined as the irreversible loss of the capacity for consciousness combined with the irreversible loss of all brain stem functions (as defined in Recommendation A.1), including the capacity to breathe".[4] These recommendations are nationally endorsed uniform NDD practice guidelines.

Taking all of these documents and initiatives together for the purpose of a post-mortem transplant, NDD appears to qualify as "accepted medical practice". Thus, it can be concluded that total brain death is a legal criterion of death under organ donation legislation in some Canadian jurisdictions (i.e., Newfoundland, Nova Scotia, New Brunswick, Ontario, Saskatchewan, Alberta, British Columbia, and the Yukon).[S]

However, the shortage of available organs for transplantation in Canada has stimulated some recent reforms to organ

[P] *Human Tissue Gift Act*, S.N.B. 2004, c. H-12.5, s. 7(1).

[Q] Quebec, Ministère de la Justice, *Commentaires du Ministère de la Justice; Code civil du Québec*, t. 1 (Quebec: Publications du Québec, 1993) at 40.

[R] Newfoundland: Human Tissue Act, S.N.L. 1999, c. H-15, s. 9(1).
Nova Scotia: Human Tissue Gift Act, R.S.N.S. 1989, c. 215, s. 8(1).
Ontario: Trillium Gift of Life Network Act, R.S.O. 1990, c. H.20, s. 7(1).
Saskatchewan: The Human Tissue Gift Act, R.S.S. 1978, c. H-15, s. 8(1).
Alberta: Human Tissue Gift Act, R.S.A. 2000, c. H-15, s. 7(1).
British Columbia: Human Tissue Gift Act, R.S.B.C. 1996, c. 211, s. 7(1).
Yukon: Human Tissue Gift Act, R.S.Y. 2002, c. 117, s. 7(1).

[S] In spite of the existence of national guidelines for NDD, a recent survey of clinical practices revealed "key diagnostic criteria for NDD were incorporated inconsistently in the guidelines from Canadian ICU's [intensive care units] and OPA's [organ procurement agencies]". *Hornby K, Shemie SD, Teitelbaum J, Doig C*. Variability in hospital-based brain death guidelines in Canada. Can J Anesth 2006; 53: 613–619.

donation protocols.[7] One such reform has been a limited adoption of CDD for organ donation. This reform was spurred by a desire to increase the number of available donor organs by permitting physicians to procure organs from individuals who do not meet the criteria for NDD, but who nevertheless meet criteria for CDD.[8] In March 2006, Ontario's Trillium Gift of Life Network indicated that one of its initiatives would be to introduce CDD organ donation,[9] and in June 2006, the first case of organ procurement from a CDD donor occurred at The Ottawa Hospital.[T] Others are currently studying the possibility of following suit.[U]

In relation to NHBD protocols, the CCDT released a report in 2005 entitled "Donation after Cardiocirculatory Death: A Canadian Forum (Report and Recommendations)", which included a recommendation for a waiting period of 5 min between the cessation of cardiopulmonary function and the pronouncement of death and retrieval of organs.[7] The CCDT report stated: "The purpose of the five (5) minute observation period is to confirm the irreversibility of cardiocirculatory arrest prior to organ procurement."[7] This recommendation creates at least three major areas of uncertainty.

The first area of uncertainty is whether the 5-min period constitutes "accepted medical practice". Indeed, this time period is not uniformly endorsed, as evidenced by the variability of international practice standards: the 1997 Institute of Medicine Report on NHBD also recommended a 5-min waiting period[10]; the Pittsburgh Protocol requires 2 min[11]; the First International Conference on Non-Heart-Beating Donors recommended 10 min[12]; and Swedish law requires that a 20-min period of asystole elapse before death is declared.[13] Within Canada, it is not clear whether hospitals establishing protocols will all adopt the CCDT 5-min recommendation or whether they will opt for alternative waiting times. It is also important to note that some hospitals that have organ transplant programs have decided against implementing NHBD protocols. For these reasons, it is not clear that the methodology applied by the CCDT forum is sufficient to justify a claim of having established "accepted medical practice" in this area.

The second area of uncertainty surrounds the justification for the 5-min period. Contrary to assertions contained within the CCDT report,[7] existing medical data do not provide sufficient empirical evidence to justify the conclusion that 5 min is sufficient to confirm the irreversibility of cardiocirculatory arrest.[14] Cardiac function can be restored by emergency resuscitation begun after a 5-min post-arrest delay,[15] and a recent review of the medical literature concluded that there is evidence that return of spontaneous circulation is possible (if exceedingly rare) up to 20 min following cessation of cardiopulmonary resuscitation (CPR).[16] In addition, suggestions that autoresuscitation (the heart restarting without any CPR) is not possible after 65 sec[17] have been challenged as having an inadequate evidentiary basis.[V]

The third area of uncertainty surrounds the role of cardiocirculatory function. If the CCDT forum assumed that irreversible cardiac arrest indicates that brain function has irreversibly ceased, then it was scientifically mistaken—brain function can continue beyond cardiac arrest.[18] If the forum assumed that irreversible cardiac arrest indicates that irreversible cessation of brain function is inevitable and

[T] *Fife R*. Ont. Organ pool to include heart failure victims. *CTV.ca News* (27 June 2006). Available from: http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20060627/organ_donation_060627?s_name=&no_ads=.

[U] The Canadian Council for Donation and Transplantation (CCDT). Donation After Cardiocirculatory Death: A Canadian Forum (Report and Recommendations) (Vancouver, British Columbia, February 17–20, 2005); The Ottawa Hospital, the London Health Sciences Centre in London, Ont., and St. Michael's Hospital in Toronto are currently implementing CDD donation programs. *Atack E*. Unique organ transplant boosts hope. (June 27, 2006) Canoe—cnews. Available from: http://cnews.canoe.ca/CNEWS/Canada/2006/06/27/1656322-cp.html. It should also be noted that some institutions in Canada have performed organ donation and transplantation after CDD in the absence of an institutional policy (indeed, in at least one instance while an institutional policy was in the process of being developed and debated).

[V] It should be clarified that uncertainty surrounding the justification for the 5-min delay—prior to certifying the death of a DCD donor—applies to both "controlled" and "uncontrolled" DCD. Existing data concerning the possibility of return of spontaneous circulation (ROSC) suggest that this uncertainty may be particularly acute in cases of uncontrolled DCD, because of the potential that attempts will have been made to resuscitate the donor. Return of spontaneous circulation following resuscitation has been documented well after the recommended 5-min waiting period. In contrast, there has never been a case report or any published data showing that ROSC has occurred after 2 min where patients have not undergone CPR (see, *DeVita MA*. The death watch: certifying death using cardiac criteria. Prog. Transplantation 2001; 11: 58–66). Nevertheless, uncertainty persists in cases of controlled DCD for at least three reasons: (1) There are no properly powered studies of autoresuscitation (the concern here is based on the statistical observation that if 200 closely monitored patients did not resume heart beat spontaneously after 5 min, there still remains a 2.5% chance that it could occur in the future. (See, *Mistry PR*. Donation after cardiac death: an overview. Mortality 2006; 11: 182–195 at 187)); (2) Data that purportedly show that ROSC has never happened after 2 min in patients' who did not receive CPR is based on results from 108 patients (data on 77 of these patients was collected more than a half century ago, and the remainder is more than 35 years old) and important policy decisions that may profoundly affect the lives of patients and their families should not be based on such an emaciated evidentiary foundation (especially given the previously noted statistical concerns); and (3) The lack of international consensus regarding the appropriate delay before organ retrieval commencement in controlled DCD situations suggests that considerable uncertainty regarding the 5-min period exists within the medical community (even among supporters of NHBD protocols, it is acknowledged that there is only "modest" evidence to support the notion that autoresuscitation following withdrawal of life support is not possible after 2–5 min. (See, e.g., *Bernat LJ*. Are Organ Donors after Cardiac Death Really Dead? J. Clin. Ethics 2006; 17: 122–132)).

imminent, then it was confusing actual death with inevitable imminent death and, mistakenly, concluding that it is acceptable to remove organs prior to actual death. If the forum took irreversible cardiac arrest to indicate irreversible cessation of cardiac function, which it took, in turn, to indicate death (independent of brain death), then it was making a dramatic move that would require substantial legal and ethical justification to support moving away from the now well-established commitment to the concept of brain death in Canada.[W] Such justification is not to be found in the report.

In the face of this degree of uncertainty, it does not appear that there is yet "accepted medical practice" with respect to CDD in the context of NHBD protocols.[X]

Problems with the legal definition and determination of death

There are a number of deficiencies with the *status quo*. These include the lack of legislative guidance in some jurisdictions, uncertainties about the definition and determination of death, conflation of the concepts of criteria and tests, confusion regarding the concept of irreversibility, and problematic implications arising from reliance on accepted medical practice.

Lack of legislative guidance in some jurisdictions

In Quebec, the Northwest Territories, and Nunavut there is no statutory definition of death or statutory criteria for the determination of death, and organ donation legislation does not provide for the determination of death "in accordance with accepted medical practice".

Uncertainty regarding the definition and determination of death

As previously mentioned, there is no federal definition of death, and at the provincial/territorial level, Prince Edward Island and Manitoba are alone in having anything even close to a legislative definition of death. In the Prince Edward Island *Human Tissue Donation Act*, death is defined as "to include brain death". This is unsatisfactory for three reasons. First, the use of the word "include" suggests that there may be multiple types of death even in this one context,[Y] only one of which is brain death. Second, the Prince Edward Island *Human Tissue Donation Act* is the only piece of Canadian provincial/territorial legislation that takes this approach. Third, brain death is not, when accurately understood, a definition of death. Rather, it is a criterion that can be used to assess whether death has occurred:

> Because they answer the question, "What does it mean for a human being to die?" definitions of death are conceptual – i.e., primarily abstract and philosophical. Criteria set the general physiologic standards for determining whether death, as defined conceptually, has occurred.[19]

In New Brunswick, it is unclear whether the *Human Tissue Gift Act* has established alternative criteria for the determination of death (neurological and other) or whether it has only set alternative medical tests that can be used to demonstrate that the criteria of death are fulfilled.

In all other provinces (except Quebec) and in the Yukon, setting the legal criteria of death (when organ transplantation is a consideration) has been left to "accepted medical practice." For the purposes of a post-mortem transplant, the question thus becomes: What qualifies as "accepted medical practice"? The answer is unclear. For the last two decades, only individuals declared dead according to neurological function have been eligible for organ donation in Canada. The CCDT Forum Report and Recommendations as well as the adoption of CDD for NHBD protocols in various jurisdictions have recently infused uncertainty into what is and is not accepted medical practice. The lack of consensus regarding the timing of death under NHBD protocols adds to the uncertainty inherent in the term "accepted medical practice."

Conflation of the concepts of criteria and tests

Discussions of the determination of death under Canadian law frequently conflate two distinct elements—the *criteria* used to determine death and the *tests* used to demonstrate that those criteria have been met. As noted by Bartlett and Youngner:

[W] The argument that death should be legally and ethically redefined in the context of organ donation has its merits and has been clearly presented by proponents of NHBD protocols in the past (see, *Truog RD, Cochrane TI*. The Truth about Donation after Cardiac Death. J. Clin. Ethics 2006; 17:133–136), but similar arguments were not advanced in the CCDT report.

[X] Acknowledging that the practice of declaring death on the basis of cardiocirculatory criteria (within 5 min or less) outside of the ICU is generally accepted does not provide support for the 5-min delay period in the DCD context. First, for the same reasons given in respect of DCD, it may not be a defensible practice; and second, when death is declared using cardiocirculatory criteria outside the context of DCD, the declaration is not followed by irrevocable actions (i.e., organ removal) which entirely preclude the possibility of ROSC.

[Y] For the purposes of this paper, we are leaving open the question of whether the case could be made to have different types of death in different contexts.

> Criteria set the general physiologic standards for determining whether death, as defined conceptually, has occurred. Once criteria have been determined, specific medical tests can be developed to demonstrate their fulfillment.[19]

It is important to carefully distinguish between *criteria* and *tests* for two reasons. First, both neurological and cardiovascular tests can satisfy neurological criteria for the determination of death, and cardiovascular tests can satisfy either neurological or cardiovascular criteria for the determination of death. Second, due mostly to the progress of science, tests are much more mutable than criteria.

Confusion regarding the concept of irreversibility

Whether determining death in relation to cessation of cardiopulmonary function or cessation of brain function, the language of irreversibility is almost always used. However, the notion of irreversibility has proven to be problematic, particularly in the context of CDD in NHBD protocols.

Cardiopulmonary function has been restored through medical interventions more than 5 min after cardiac arrest.[15] Return of spontaneous circulation has also been documented up to 20 min after ending cardiopulmonary resuscitation (CPR).[16] And yet, if a patient or substitute decision-maker has refused CPR, health care professionals are not legally permitted to attempt to restart the heart. In this circumstance, there is a lack of cogent evidence to support the assertion that return of spontaneous circulation is not possible after 2 min (see footnote V). These facts taken together set the stage for confusion about the definition and determination of death.[20]

The Oxford English Dictionary defines "irreversible" as something "that cannot be undone".[21] The problem is that the word, "cannot", can have at least two meanings—namely, "is not possible" and "is not permitted". In some circumstances, cessation of cardiopulmonary function can be reversed from a medical or scientific perspective (it is physically possible) but, given the common law—and sometimes statutory—requirement to respect a patient's wishes, cannot be reversed from a legal perspective (it is not permitted).

If irreversible means "cannot be reversed", understood as "not physically possible to reverse", then a physician should not declare death until it is physically impossible for the heart to be restarted (either through CPR or spontaneously). If irreversible means "cannot be reversed", understood as "not physically possible to reverse without violating the law on consent", then death can be declared immediately after any one of three points depending on the circumstances: (1) if there has been no CPR and there has been a valid refusal of attempted resuscitation, at the point at which autoresuscitation is not possible; (2) if there has been CPR and there has been a valid refusal of restarting CPR, at the point at which spontaneous return of circulation post-CPR is not possible; and (3) at the point at which restarting the heart (either through CPR or spontaneously) is not physically possible. It is not at all clear what meaning of "cannot be reversed" is being assumed in the current usage of the concept of irreversibility.

Reliance on "accepted medical practice"

In most provinces (excluding Manitoba and Quebec) and in the Yukon, organ legislation specifies that death must be determined "in accordance with accepted medical practice". This is problematic. Effectively, it leaves the legal nature of death to be determined by the medical community. Although this should be the case for the medical tests of death, the legal definition and criteria of death should be set by lawmakers. It is the role of the law to set the definition of death and the criteria by which death is measured (although both will be informed by medicine and philosophy), and it is the role of medicine to determine whether the legal criteria of death are satisfied. These conclusions are supported by two arguments.

First, the definition of death in law must be understood as a discrete event. From a legal perspective, we need to be able to declare the moment of death (for the purposes of determining whether particular things, such as burial or organ procurement, can be done to the body). And yet, from a medical perspective, by contrast, death is more appropriately conceived as a process. There may be no biological "moment of death".[22]

Our second argument is that a legal function (such as the ascription of rights or social values) requires a legal definition and legal determination. An analogy may be helpful here. "Mental disorder" is a concept used in the *Criminal Code*, as there is a defence of mental disorder (one can be found not criminally responsible "for an act committed or an omission made while suffering from a mental disorder that rendered the person incapable of appreciating the nature and quality of the act or omission or of knowing that it was wrong").[Z] While it might, on the face of it, appear that "mental disorder" should be defined and determined by the medical profession, because of the legal implications of the determinations, for the purposes of the *Criminal Code*, it is considered a legal concept subject to determination by the legal system. Similarly, "accepted medical practice" should be considered relevant for the tests for determining death but not for the definition or criteria.

[Z] *Criminal Code*, R.S. C, 1985, c-46, s. 16.

Recommendations regarding law and policy on eligibility for post-mortem organ donation

In a 1981 report on the criteria for the determination of death, the Law Reform Commission of Canada recommended that the criteria for the determination of death be legislated.[AA] The Commission considered leaving the medical profession or the common law to develop the criteria for death but reasoned that both of these avenues were unacceptable. The main argument in support of leaving the criteria to be set by the medical profession was a "fear that the case law or legislative approaches would transform what is fundamentally a medical reality (the death of a human being) into a legal one, and thus create a risk of impeding the progress and development of medical science" (see footnote AA). Although the Commission recognized this as an understandable concern, it ultimately found the concern to be "based on a misconception and exaggeration of the role and dangers of legal intervention" (see footnote AA) and concluded that the option of leaving the criteria of death to the medical profession was "unreasonable and unrealistic" (see footnote AA). It must be emphasized here that the Commission did not propose that the law define the specific medical tests used in the determination of death, nor is this what we are suggesting. Medical tests should be left to the medical profession. This will allow for the tests to evolve according to the progression of science and medicine.

The Commission also provided arguments against leaving the criteria for the determination of death to case law:

> [First] this solution achieves nothing else than the perpetuation of the present state of uncertainty surrounding both the concepts of death and the basic principles of its determination… [Second] a judicial debate in a courtroom is not the proper forum for a scientific discussion of the problem of criteria of death objectively detached from the contingencies of the particular case at hand. The standards should be determined in a scientific and unemotional way. A "test case" should not be necessary to the progress and development of the law on the matter. (see footnote AA)

For these reasons, as well as the reasons outlined in the preceding section on the reliance on "accepted medical practice" for anything beyond tests, we recommend that the legal nature of death be legislated. We also recommend that both the criteria for determining death and a definition of death be included in the legislation. This approach would have two main advantages. First, a definition of death is needed in order to develop coherent criteria for the determination of death. This definition should be made explicit so that the justification for the chosen criteria is apparent. Second, having both a legal definition of death and separate legal criteria for the determination of death would provide conceptual clarity—it identifies them as two distinct elements, a point that is often overlooked.

In our view, the statutory definition of death should be the *irreversible* cessation of the functioning of the *organism as a whole*. In this regard, there are two dominant competing definitions of the death of a human being. The first defines death as the cessation of the functioning of the organism as a whole.[23] The second defines death as the "loss of that which is considered to be essentially significant to the nature of man".[24] Under the second definition of death, consciousness is the essential characteristic of human beings. This definition has thus become known as the "higher-brain formulation of death".[25]

Advocates of the first definition of death (organism as a whole) find the higher-brain formulation to be inadequate for four main reasons.

> First, and most importantly, this definition is not what society means by "death", because its application would declare dead the thousands of patients in persistent vegetative states and other forms of permanent unconsciousness who are regarded as alive in every society and jurisdiction in the world. This fact reveals that the higher-brain formulation is not an attempt to make explicit the traditional concept of death but to contrive a radical redefinition of death. Second, applying the higher-brain formulation creates a serious slippery slope problem in which the criterion for death becomes indistinct. If patients in persistent vegetative states were considered dead, perhaps so should severely demented patients, because they too lack experiential and social integration functions. Third, the definition is non-univocal and cannot be applied to other higher animals, because it was devised solely for Homo sapiens. Finally, practical problems would arise if spontaneously breathing patients in persistent vegetative states were buried while maintaining these vital functions.[26]

For these reasons, we too recommend that the statutory definition of death refer to the functioning of the organism as a whole.

While the choice between the two dominant competing definitions of death is relatively straightforward, the substance of the concept of "the organism as a whole" is considerably more elusive. The key question is, "What makes this particular set of cells a singular organism as opposed to a mass of cells that happen to more or less

[AA] Law Reform Commission of Canada (LRCC), Criteria for the Determination of Death (Working Paper No. 23) Ottawa; The Commission: 1979.

adhere to one another?" We would argue that, fundamentally, the answer to this question is the characteristic of control and coordination as it applies to an organism's critical functions. The critical functions of human beings have been described as respiration and circulation, endocrine and homeostatic regulation, and consciousness.[25,26] The irreversible loss of the control and coordination of all critical functions is therefore the necessary and sufficient condition for the conclusion that there is no longer an "organism as a whole".[BB]

In order to escape the problems identified above with respect to the concept of "irreversibility", it has been suggested by some that the language of permanence replace that of irreversibility.[20] The Oxford English Dictionary defines permanent as "continuing or designed to continue indefinitely without change".[21] The use of "permanent" in a legislative definition, it is argued, would allow death to be declared when it is clear that the heart will not be restarted (owing to medical impossibility, legal impermissibility, or other reasons). This terminology is said to avoid the problems associated with the existence of more than one possible interpretation of the term "irreversible". However, the problem of two possible interpretations applies as much to "permanent" as it does to "irreversible". Therefore, we do not suggest changing the terminology used. Rather, we recommend very clearly defining the terminology in the legislation. This definition, we recommend, would be "not physically possible to reverse without violating the law on consent" (as this captures the physical possibility of restoration of function coupled with a refusal of the treatment necessary for restoration). Of course, with reference to consent law, this definition makes death a partly social construct. We feel that this is appropriate and correct, given that this is a legal definition fulfilling a legal purpose.

It is also our view that the statutory criterion for the determination of death should be the *irreversible* loss of the brain's capacity to control and coordinate the organism's critical functions. A criterion for the determination of death must be a measurable condition that satisfies the definition of death by being both necessary and sufficient for death.[26] The four commonly proposed criteria are whole brain function, higher brain function, brain stem function, and cardiopulmonary function. On our interpretation, both the higher brain and brain stem criteria are necessary but not sufficient, and the cardiopulmonary criterion is sufficient but not necessary.[26]

Whole brain function could be interpreted as meaning any and all brain function or the coordinated functioning of the brain as a whole. Under the latter interpretation, whole brain death occurs when there is no upper brain or brain stem activity of the type needed for the brain to execute its vital role in supporting the physiologic activity necessary to sustain an organism's critical functions. Bernat has described this idea as follows:

> Destruction of a critical array of neurons within the "whole" brain (hemispheres, diencephalon, and brain stem) is necessary for death because: (1) the vital functions of respiration and control of circulation are subserved by the brain stem; (2) the critical integrative functions are subserved by both the brain stem and hypothalamus; and (3) the wakefulness component of consciousness is subserved by the brain stem and the awareness component of consciousness by the thalamus and cerebral cortex. A whole-brain criterion is required because, although both a higher brain and a brain stem criterion are necessary for death, neither alone is sufficient for death.[26]

This interpretation recognizes that the brain can lose its capacity to support physiologic activity, even though residual neural activity may be present and detectable (for this reason, whole brain function should not be interpreted as meaning any and all brain function). We therefore recommend that the statutory criterion for the determination of death should be the irreversible loss of the brain's capacity to control and coordinate the organism's critical functions.

We recommend that legislation explicitly state that all three tests (neurological, cardiopulmonary, and cerebral blood flow) and any others subsequently developed are directed towards determining a single criterion of death, and that the use of the three or more tests does not establish alternative criteria for the determination of death.[CC]

It is the role of the medical profession to establish which specific medical tests for determination of death should be used.

We furthermore suggest that the definition of death and the criterion for the determination of death should be contained in federal and provincial interpretation acts. In 1981, the Law Reform Commission of Canada considered four statutes as potential locations for the criteria of death.

[BB] This understanding of the concept of an "organism as a whole" (i.e., one that is anchored by the control and coordination of critical functions) accommodates the possibility that death has occurred in spite of the fact that isolated organs retain the capacity to function—this is an essential accommodation as it forms the very basis for post-mortem organ donation (i.e., a dead donor who possesses organs that maintain the capacity to function within a suitable recipient).

[CC] It is important to note that cardiopulmonary tests will legitimately continue to be frequently used (especially when people die outside the ICU), but it is also important to emphasize that these cardiopulmonary tests are to determine whether neurological criteria, not cardiological criteria, have been met.

The Commission rejected placing the criteria in the *Criminal Code* (which applies only to criminal law) and found the *Canada Evidence Act* to be an inappropriate location, because the criteria of death "is not a simple rule of evidence and would not apply only in cases of contentious matters before criminal and civil courts" (see footnote AA). The Commission also concluded that enacting a specific piece of legislation to contain the criteria of death was not necessary. Ultimately, the Commission concluded that the definition and criteria of death should be embedded in the federal *Interpretation Act*,[DD] because it applies to federal law as a whole.

For the same reasons, we endorse the recommendations of the Commission with regard to locating the definition of death and criterion for determining death in the federal *Interpretation Act*. Additionally, we recommend that provincial/territorial interpretation acts be amended to include the definition of death and the criterion for the determination of death (as these cover the interpretation of all provincial statutes and regulation, and organ donation and transplantation is managed in Canada through provincial/territorial legislation). Interpretation acts are preferred over organ donation legislation because they provide for greater consistency in the definition of key terms across various legal contexts (leaving open the possibility that the case could be made in very particular contexts for the use of a different definition and criteria in specific statutes—noting, however, that the burden would then be on those who seek a different definition and criteria to expressly address the matter and justify the proposed difference).[EE]

Incorporating the following text in federal, provincial, and territorial interpretation acts would address the concerns raised above:

> Except where otherwise explicitly stated in legislation enacted subsequent to [insert date of amendment], for all purposes within the jurisdiction of the Parliament of [insert name of jurisdiction],
>
> (1) Death is defined as the irreversible cessation of the functioning of the organism as a whole.
> (2) The criterion for the determination of death is the irreversible loss of the brain's capacity to control and coordinate the organism's critical functions.
> (3) Irreversible is defined as not physically possible to reverse without violating the law on consent.
> (4) The fulfillment of the criterion may be demonstrated by one or more medical tests. Specific tests are to be established by the medical profession.

We recognize that, for political or pragmatic reasons, governments may be more willing to open their organ and tissue legislation rather than their interpretation acts. While we believe that the interpretation acts are the better homes for the definition of death and the criteria for the determination of death (for the reasons outlined above), we acknowledge that organ and tissue acts are a second-best home. If legislatures prefer to go the route of organ and tissue legislation, we recommend that the text provided above be included in them minus the prefatory clause re: jurisdiction.

Practical implications for NBHD protocols and practice

Current Canadian law on the definition and determination of death, although lacking consistency and conceptual clarity, primarily endorses a definition of death that equates whole brain death with legal death. According to this reading of Canadian law and the available scientific evidence cited above, the CCDT's recommended national guidelines for NHBD protocols may violate the dead donor rule (explained in the Introduction) for two reasons. First, there may be a possibility of return of spontaneous circulation in a patient who has been asystolic for 5 min. Second, even in the absence of the return of spontaneous circulation, there is evidence that the brain may not necessarily suffer irreversible loss of its capacity to control and coordinate the organism's critical functions after a 5-min period of global brain ischemia. Therefore, the possibility remains that some NHBD donors may not be legally dead under prevailing Canadian laws.

The recommendations advanced in this paper are consistent with current Canadian law and advocate loss of neurological function as the legal criterion for death. Critically, however, the recommendations go one step further by defining irreversible to mean "not physically possible to reverse without violating the law on consent". Under this definition of irreversibility, the recommendations limit but do not exclude the possibility of NHBD protocols in Canada. NHBD protocols would be legally permissible in situations where the donor has made an informed decision not to be resuscitated and where it is clear that neither autoresuscitation nor post-CPR spontaneous return of circulation is possible.

Unfortunately, as described above, there is insufficient clinical data to support the CCDT's assertion that return of spontaneous circulation is not possible after 5 min of asystole (see footnote V).[14,27] In this age of evidence-based

[DD] *Interpretation Act*, R.S.C. 1985, c. I-21.

[EE] We do not see an argument for any different definition or criteria in any specific legal context, but cannot logically prove that there could not be such an argument ever made and so have chosen to leave this possibility open.

medicine, the onus must rest on those seeking to introduce NHBD protocols in Canada to provide both lawmakers and the public with compelling evidence on which to ground their recommendation concerning the timing of declaration of death. This evidence has not been forthcoming. Gathering this evidence is therefore an essential step toward solidifying the foundation on which donation after cardiocirculatory death (DCD) could move forward in Canada. Until this evidence is collected (or until a concrete proposal to abandon the dead donor rule and amend Canadian law is adopted following a process of public debate and intense multidisciplinary review) the current use of NHBD donor protocols in Canada will remain inconsistent with Canadian law.

Summary

Before closing, it is important to explicitly revisit the concerns motivating this paper. Would the changes recommended above help to improve the legal situation in Canada with regard to the definition and determination of death? We believe that the answer to this question is yes. Consider each in turn.

Health care provider fear of liability—clarity about the definition and determination of death could greatly reduce health care provider fear of liability. Clear protocols for declaring death could be developed, and health care providers could have confidence that they would not be found liable if they followed the protocols.

Public lack of confidence in the determination of death—clarity about the definition and determination of death could enhance public confidence. Again, clear statements in law and clear protocols for medical practice could give the public confidence that their organs would not be removed until after they are dead.

NHBD protocols—adoption of the recommended definition and criteria for determination of death would lead to NHBD being legally permissible if (but only if) the following three conditions are met:

(1) There has been a valid refusal of CPR by the patient directly or indirectly through an advance directive or through the patient's legally authorized substitute decision-maker; and

(2) a. If no CPR has been performed, death may be declared at the point at which there is no chance of autoresuscitation.

b. If CPR has been performed, death may be declared at the point at which there is no chance of spontaneous return of cardiac function; and

(3) There is no possibility of reperfusion of the donor's brain (reperfusion of other organs is permissible).

Conclusions

Recent developments in transplantation medicine have provided a potent rationale for this review of the state of Canadian law as it relates to the definition and determination of death. At present, an inadequate patchwork sustains a climate of legal uncertainty.

The medico-legal deficiencies regarding the definition and determination of death undermine the efforts of health care practitioners who, in good faith, have sought to develop and implement DCD protocols as a means for helping critically ill patients. Also, they may place health care workers at risk of civil or criminal liability, discourage potential organ donors, frustrate the wishes of some individuals to donate their organs, and open the door to high-cost litigation as issues related to death find their way before the courts. The issues raised in this paper (including, not least, the data on the public confidence in the determination of death and the legal permissibility of NHBD protocols) suggest a pressing need for legislative reform.

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