



# Rationale for revisions to the definition of death and criteria for its determination in Canada

## Justification des révisions apportées à la définition du décès et à ses critères de détermination au Canada

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**Abstract** Clarity regarding the biomedical definition of death and the criteria for its determination is critical to inform practices in clinical care, medical research, law, and organ donation. While best practices for death determination by neurologic criteria and circulatory criteria were previously outlined in Canadian medical guidelines, several issues have arisen to force their reappraisal. Ongoing scientific discovery, corresponding changes in medical practice, and legal and ethical challenges compel a comprehensive update. Accordingly, the A Brain-Based Definition of Death and Criteria for its Determination After Arrest of Neurologic or Circulatory Function in Canada project was undertaken to develop a unified brain-based definition of death, and to establish criteria for its determination after devastating brain injury and/or circulatory arrest. Specifically, the project had

three objectives: (1) to clarify that death is defined in terms of brain functions; (2) to clarify how a brain-based definition of death is articulated; and (3) to clarify the criteria for determining if the brain-based definition is met. The updated death determination guideline therefore defines death as the permanent cessation of brain function and describes corresponding circulatory and neurologic criteria to ascertain the permanent cessation of brain function. This article explores the challenges that prompted revisions to the biomedical definition of death and the criteria for its determination and outlines the rationales underpinning the project's three objectives. By clarifying that all death is defined in terms of brain function, the project seeks to align guidelines with contemporary medicolegal understandings of the biological basis of death.

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Clarity regarding the biomedical definition of death and the criteria for its determination is critical to inform practices in clinical care, medical research, law, and organ donation.<sup>1,2</sup> Health care professionals need to know the physiologic criteria of death, how to evaluate whether these criteria are met, and—in the context of critical care—whether medical interventions constitute treatment as opposed to mechanical support for deceased persons' bodies (“somatic support”). Hospitals need to know if patients are alive or dead for triage and resource allocation; researchers need to know to afford living participants research protections; and surrogates need to know for informed decision-making. Moreover, the death of a person has social and legal implications, including family grieving, resource allocation, insurance proceeds, and estate settlement. Finally, the need for clarity on the boundary between life and death is particularly acute in the context of deceased organ donation, where organ recovery for transplantation is contingent on accurate and timely death determination. Hence, clarity and uniformity regarding the biomedical definition of death and the criteria for its determination are of profound importance to a range of Canadian stakeholders.<sup>3</sup>

The concept of death has long been the subject of empirical, religious, cultural, and philosophical debate. Examples of conceptualizations range from the quasiphiologic “permanent cessation of the organism as a whole”<sup>4</sup> to the religiously informed “moment the soul leaves the body.”<sup>5</sup> While respectfully recognizing the spectrum of perspectives on the concept of death, the exigencies described above show how the medical community requires a legally recognized, biomedical, “operational” definition of death to guide practice. An operational definition is a concrete formulation describing the state of human death based on measurable and observable biological indicators—i.e., a practical formulation entailing criteria for death determination concordant with that definition.<sup>6</sup> As a practical formulation, the definition of death explicated in this article is defended largely on consequentialist grounds and ultimately reliant upon consensus as opposed to metaphysical argument. The metaphysical implications of this definition are addressed elsewhere in this Special Issue.<sup>7</sup>

The recently updated Canadian guidelines for death determination featured in this month's Special Issue of the *Journal*<sup>2</sup> define death as the permanent cessation of brain function and provide corresponding circulatory and

neurologic *criteria* to ascertain the permanent cessation of brain function.<sup>2</sup> For the purposes of clarity, it bears emphasizing that an operational definition of death and the criteria for its determination are distinct. While an operational definition describes the necessary and jointly sufficient conditions for death, the criteria describe the biological indicators used to determine whether these conditions are met. For this reason, the biomedical definition is conceptually prior to the criteria. That is, the criteria rely on the definition for their legitimacy—hence the importance of an operational definition of death for medical practice.

While best practices for death determination by neurologic criteria (DNC)<sup>8</sup> and circulatory criteria (DCC)<sup>9,10</sup> were previously outlined in Canadian guidelines, several issues have arisen to force their reappraisal. Regarding the *criteria* for death determination (i.e., observable and measurable biological indicators), guidelines should ideally be revisited every three to five years.<sup>11,12</sup> Given that current practices are based on guidelines published in 2006, an update is overdue.<sup>8,9</sup> An evolving evidence base, advances in ancillary testing techniques, and recently published international guidelines for death determination reinforce this conclusion.<sup>13</sup> Moreover, ambiguity in the meaning of terms integral to the criteria for death determination (e.g., “perfusion,” “flow,” “function”),<sup>14</sup> combined with a recognition that consequent variable adherence to best practice may undermine confidence in medicine,<sup>15</sup> suggest an updated guideline that resolves lingering ambiguities will be welcomed by the medical and legal communities.

Regarding the operational, biomedical *definition* of death, persisting controversy<sup>16</sup> surrounding the meaning of terms integral to the definition may be allayed by elucidating their precise meanings in the context of medical practice and law. Moreover, confusion regarding the conceptual relationship between circulatory and neurologic criteria for death determination<sup>17,18</sup> indicates that clarifying what unites these sets of criteria is warranted. Additionally, variation in provincial legislative regimes governing death's definition underlines the need for national uniformity;<sup>19</sup> a biomedical definition within a nationally endorsed medical guideline may encourage the required unification. Finally, innovations in health care continue to illuminate the shortcomings of previously accepted definitions of death in the same way that mechanical ventilators spurred the recognition of neurologic death over fifty years ago.<sup>20</sup> Driven by advances in medical technologies like the ventilator (which can artificially sustain cardiorespiratory function when neurologic function is lost), as well as an increased understanding of the physiology of the dying process, a growing medical and societal consensus holds that, from a

biomedical perspective, all death is brain-based.<sup>21</sup> Updated medical guidelines should therefore reflect the centrality of the permanent loss of brain function for death determination.

Accordingly, the *A Brain-Based Definition of Death and Criteria for its Determination After Arrest of Neurologic or Circulatory Function in Canada* project was undertaken to develop a unified brain-based definition of death, and to establish criteria for its determination after devastating brain injury and/or circulatory arrest.<sup>2</sup> Specifically, the project had three objectives:

Objective 1: To clarify that death is defined in terms of brain functions (i.e., although criteria for DCC and DNC differ, both are means to identify the same phenomenon: permanent loss of brain function).

Objective 2: To clarify how a brain-based definition of death is articulated (i.e., the precise meanings of all terms integral to the definition of death).

Objective 3: To clarify the criteria for determining if the brain-based definition is met (i.e., the objectively measurable criteria, procedures, or ancillary tests that must be taken to satisfy the definition and the precise meanings of all terms integral to these criteria).

Objectives 1 and 2 concern the biomedical *definition* of death and its articulation. Objective 3 concerns the *criteria* for death's determination and their articulation.

This article explains the rationale underpinning each of the above objectives. Because of the logical priority of an operational definition of death for medical practice, as well as the uncontroversial need for an evidence-based update to criteria for death determination, expositing the rationales supporting objectives 1 and 2 is the principal aim. In what follows, we first provide a brief overview of the medical and legal evolution of death's definition and practices for its determination over the last several decades. We then describe the rationales for the above objectives.

## Background

The advent of novel resuscitative measures and organ-supporting technologies in the 1950–1960s challenged then contemporary understandings of death based on cessation of circulation and respiration.<sup>20</sup> The ability to restore and maintain these vital functions in patients who had lost brain function blurred the previously bright line between life and death,<sup>17</sup> exposed the shortcomings of existing criteria for death determination, and raised complex ethical and legal issues. Among the latter were concerns over the perceived misuse of scarce health care resources, controversy over the permissibility of withdrawal of organ-supporting

measures, and doubts about the legality of recovering transplantable organs from individuals who had lost all brain function.<sup>20</sup>

In 1968, the Ad Hoc Committee of Harvard Medical School issued a report establishing criteria for death determination based on “irreversible coma,” or total loss of brain function.<sup>20</sup> By the 1980s, the term “brain death” to describe the total loss of brain function had gained currency, and criteria for DNC were increasingly accepted by medical professionals.<sup>22</sup> Yet, stimulated by the need for greater certainty in the face of variable practices and legislation governing death's definition and determination, commissions in both the USA and Canada convened to determine whether a brain-based definition of death ought to be enshrined in law.

The 1981 US President's Commission recommended that states adopt its proposed *Uniform Determination of Death Act* (UDDA), a statute describing legal death, to avert the uncertainty and inconsistency that would result if none were adopted.<sup>5</sup> The commission did not recommend a unified brain-based definition of death, but instead confined its recommendations to the level of general physiologic standards for death determination.

The commission proposed that alternative circulatory/respiratory and neurologic standards ought to feature in the UDDA for two reasons. First, the projected incidence of neurologic death was low, meaning that the circulatory/respiratory standard would remain adequate in the overwhelming majority of cases. Second, supplementing rather than supplanting the traditional cardiorespiratory approach to death determination was thought to be more acceptable from a societal perspective.<sup>A</sup> Nonetheless, the authors of the report warned that “the use of two standards in a statute should not be permitted to obscure the fact that death is a unitary phenomenon.”<sup>5</sup>

In contrast to the US President's Commission, in 1981 the Law Reform Commission of Canada (LRCC) recommended that a single, unified, brain-based definition of death be enshrined in legislation.<sup>3</sup> The commission averred that “a person is dead when an irreversible cessation of all that person's brain function has occurred,” but allowed that this could be inferred based on either circulatory/respiratory criteria or, when organ-

<sup>A</sup> “Conservatism seems justified in articulating a rule that will not only be applied within the legal system but will also guide the beliefs and behavior of physicians and the public. People's attitudes toward death evolve, and changes in medical capabilities certainly come to be reflected in public as well as professional circles: heart transplantation, for example, cannot help but alter the romantic notion of the heart as the seat of soul or personality. Change does not occur overnight, however, and there seems to be no reason to force it by statute when wrenching change is not necessary. Any statute on death should, therefore, supplement rather than supplant the existing legal concept.”<sup>5</sup>

supporting technologies are in place, by neurologic criteria.<sup>3</sup>

Despite strong endorsement by the Canadian Medical Association and a host of other medical professional organizations, Parliament did not follow the LRCC's 1981 recommendation (although the Manitoba legislature did). This resulted in a patchwork of legal approaches in the common law and legislation governing death's definition in the Canadian provinces and territories.<sup>19</sup>

### Rationales for the project's objectives

Various challenges have arisen to force a reassessment of existing medicolegal definitions of death and criteria for death's determination in Canada. In what follows, we outline the rationales for the guideline development group's three objectives.

#### *Objective 1: To clarify that death is defined in terms of brain function*

The updated death determination guideline defines death as the "permanent cessation of brain function."<sup>2</sup> While this definition affirms the centrality of the cessation of brain function for human death, it is worth emphasizing that the guideline does not render circulatory criteria for death determination obsolete. Instead, it seeks to clarify that circulatory criteria are reliable proxy indicators for the permanent loss of brain function. In doing so, the guideline defines all death for the purposes of medical practice in terms of brain function, regardless of whether the permanent loss of these functions is ascertained by circulatory or neurologic criteria.

#### COHERING WITH CONTEMPORARY BIOMEDICAL AND LEGAL UNDERSTANDING OF DEATH

Over the past 70 years, evolving medical technologies and greater insight into the physiology of the dying process have forced the reassessment of operational definitions of death and criteria for its determination.<sup>23</sup> Advances in life-support technologies, resuscitative techniques, organ donation and preservation, as well as breakthroughs in our understandings of cell biology and physiology have combined to clarify the physiologic mechanisms of death in humans.<sup>21</sup> Shemie and Gardiner describe the three most common pathways:

1. Primary or secondary brain event with cessation of brain function, most often associated with intracranial hypertension and cessation of brain blood flow, leading

to apnea, hypoxemia, cardiac arrest, and cessation of circulation.

2. Primary or secondary respiratory event causing hypoxemia resulting in cardiac arrest and cessation of circulation to all organs including the brain.
3. Primary or secondary cardiac event resulting in cardiac arrest and cessation of circulation to all organs including the brain.<sup>21</sup>

In the past, the loss of any one vital system would inevitably result in the loss of the others. If brain function failed, loss of cardiorespiratory function would swiftly follow. If cardiorespiratory function failed, loss of brain function would swiftly follow. If other vital organs or systems failed, cardiorespiratory function and, consequently, brain function were inevitably lost. Nevertheless, it is now possible to sustain and/or replace organ function for all vital organs and systems except the brain.<sup>21</sup> Indeed, in the effort to save life, the dying process is regularly interrupted by the use of intrinsic or extrinsic organ-supporting technologies such as mechanical ventilation, hemodynamic support of cardiovascular function, extracorporeal membrane oxygenation (ECMO), and ventricular assist devices (VAD).<sup>21</sup> It is the introduction and use of technologies like these in health care that spurred previous refinements to the definition of death and criteria for its determination, and which have pushed the medical community and society in general progressively closer to a brain-based definition of death.<sup>24</sup>

The growing consensus on the importance of brain function for contemporary biomedical understandings of death is shown by the way individuals supported with technologies like ECMO, VADs, and mechanical ventilation are perceived and treated in both medical practice and law. Provided brain function persists, patients whose organs or systems are maintained using these technologies are indisputably considered alive. Nevertheless, the same technologies that enable patients to survive after vital organ or system failure also enable circumstances in which vital systems are maintained in individuals who have permanently lost brain function. Although they display some signs characteristic of life (e.g., mechanically supported heart and lung function), most health care professionals consider such individuals deceased.<sup>17,25</sup> This position is legally recognized in many jurisdictions internationally<sup>25</sup> and is upheld throughout Canada by the legal acceptance of brain death—i.e., a legal recognition that a person who has sustained permanent loss of brain function is deceased despite maintenance of cardiorespiratory function.<sup>19</sup>

These observations reflect the central importance of brain function for contemporary biomedical and legal concepts of human life and death, concepts refined and



informed by advances in medical technology. Clarifying that for the purposes of medical practice all death is defined in terms of brain function will establish an accurate definition that coheres with the contemporary medicolegal understanding of death.

#### UNIFORMITY

Currently, Manitoba, Newfoundland and Labrador, and Nova Scotia have legislated brain-based definitions of death. Manitoba's *Vital Statistics Act*, for instance, states that "...the death of a person takes place at the time at which irreversible cessation of all that person's brain function occurs."<sup>26</sup> In New Brunswick, the Northwest Territories, and Prince Edward Island, death is legally defined in terms of both brain-based and circulatory/respiratory criteria. In New Brunswick, for example, "the fact of death is determined in accordance with neurologic criteria, or ... by other criteria."<sup>27</sup> In all other provinces and territories, there is no legislated definition of death. In these jurisdictions, the legal definition of death has been developed through the courts, which have accepted both brain-based and circulatory/respiratory definitions.<sup>19,28</sup> In most provinces and territories, organ and tissue donation legislation specifies that, for the purposes of organ donation, death must be determined "in accordance with accepted medical practice."<sup>19</sup>

The 1981 LRCC report noted that "criteria for the determination of death represent a very real and practical problem for many practicing physicians and hospital personnel," and added that the issue was of concern to several other stakeholders, including medical institutions, professional medical and legal organizations, and the public.<sup>3</sup> Indeed, pervasive confusion, ambiguity, and uncertainty concerning death's definition and determination were the primary reasons for the report's inception. Urging the federal government to ensure uniformity in legislation across provinces and territories, the report argued that a unified brain-based definition of death would provide the clarity sought by stakeholders.

The LRCC's position concerning the benefits of uniformity is no less valid today than it was 40 years ago. Indeed, it is reinforced by continuing advances in medical technologies and increasing consensus on the centrality of brain function in law and medicine. The death of a person is an event with significant social and legal implications.<sup>29</sup> It is confusing and inexpedient to have apparent variation on a fundamental point so central to societal and medical practices.<sup>30</sup> As seen in the USA, variability may undermine public trust in the legitimacy of practices for death determination, particularly with regard to DNC in the context of organ donation.<sup>31</sup> Setting aside the question of whether a brain-based definition of death

ought to be uniformly enshrined in legislation, a unified brain-based definition within a nationally endorsed medical guideline will help to allay confusion by clarifying that, for the purposes of medical practice, all death is defined in terms of brain functions, and strengthen public confidence by promoting consistency across provinces and territories.<sup>B</sup>

#### PUBLIC AND PROFESSIONAL CONFUSION

There remains professional disagreement<sup>17,32–36</sup> and public confusion<sup>18,37</sup> regarding the contemporary biomedical understanding of death and, consequently, the conceptual and physiologic relationship between circulatory and neurologic criteria for death determination. Clarifying what unites these apparently disparate criteria is necessary to help allay stakeholder misgivings regarding death determination in the context of medical practice and organ donation.

Although there have been few studies on stakeholder perceptions of DCC, it is clear from studies of perspectives on the legitimacy of DNC that confusion regarding the biological basis of death exists.<sup>17,37</sup> In its 1981 report, the LRCC noted that:

... a very large proportion of the Canadian public would like to see removed the present ambiguity arising from the apparent contradiction between the classical signs of death (cessation of cardiac and respiratory functions) and the neurologic signs (irreversible cessation of all brain functions).<sup>3</sup>

Unfortunately, this "present ambiguity" persists, and continues to pervade stakeholder understandings.<sup>38,39</sup> Fractured discourse in medical literature,<sup>40</sup> highly publicized legal challenges to brain death determination,<sup>31</sup> and misrepresentations of brain death in the media<sup>41</sup> lead some to believe that brain death is not "real" death,<sup>42,43</sup> others to think that criteria for DNC are more reliable than criteria for DCC in the context of organ donation,<sup>44,45</sup> and others to think that criteria for DCC do not reliably describe death at all.<sup>16</sup>

Although the two pathways to death determination identify the same phenomenon (death), the bifurcated standard for death determination and its associated terminology ("brain death" and "circulatory death") may lead some to erroneously conclude that there are two recognized types of death.<sup>6,43</sup> This inference is supported by the practically reasonable but inadvertently misleading tendency of guidelines for death determination to define

<sup>B</sup> To the extent that the proposed single brain-based definition of death refers to the loss of "brain function" as opposed to "all brain function," it will be necessary to explain how the proposed definition will be consistent with existing law. See the article by Chandler and Pope on legal implications in this Special Issue.<sup>19</sup>

circulatory and neurologic death in isolation from one another. In short, the bifurcated standard continues to erroneously suggest that the two pathways to death determination do not point to the same thing: the permanent loss of brain function.

Growing recognition in the medical community of the centrality of brain function for human life<sup>6,21</sup> helps to explain why brain death is widely accepted among health care professionals.<sup>17,25</sup> Debates regarding the legitimacy of DNC are largely confined to academic circles, and there is little evidence that these debates have impacted the broader medical community's acceptance of the concept.<sup>46</sup> Indeed, a recently published scoping review concluded that DNC is largely uncontroversial in practice.<sup>17</sup> Nevertheless, confusion concerning brain death's conceptual basis remains.<sup>17</sup> As recently as 2007, 45% of surveyed Canadian neurosurgeons responded "no" when asked whether circulatory and neurologic criteria describe the same phenomenon: the death of the patient.<sup>47</sup> While more recent data are not available, professional disagreement over the validity of brain death remains evident in academic literature.<sup>48–50</sup> Moreover, the variability of practices for death determination across Canada points indirectly to continued uncertainty and disagreement among health care professionals over the biological basis of death.<sup>13,51–53</sup> Calls for increased education and standardization highlight the need to clarify this biological basis for the benefit of practicing health care professionals.<sup>17</sup>

The ongoing controversy arising from highly publicized legal objections to DNC may help to explain persistent uncertainty among the lay public about brain death.<sup>18,37</sup> Although the Canadian public is generally aware and accepting of brain death, understanding of the concept is limited.<sup>37</sup> This confusion has implications for medical practice and organ donation. In both Canada and the USA, roughly half of surveyed physicians report having had the experience of a surrogate decision-maker requesting continued somatic support following DNC; many requests are honored temporarily in an effort to support grieving families.<sup>54,55</sup> Whether this phenomenon reflects opposition to brain death or just confusion is unknown. Nevertheless, at least in the USA, opposition to brain death appears to be growing.<sup>13,31,44</sup> For families of brain-dead individuals, the cognitive dissonance involved in acknowledging that a body displaying some signs characteristic of life is nonetheless deceased contributes to distress stemming from what has been termed "paradoxical death."<sup>37,56</sup> Public confusion about the biological basis of death may lead to anxiety and uncertainty among families of brain-dead individuals,<sup>13,37,57</sup> moral distress in health care professionals asked to provide futile somatic support that

they consider disrespectful to the body of the deceased,<sup>58</sup> and, potentially, the misuse of scarce health care resources.<sup>59</sup> In turn, the uncertainty at the root of opposition to DNC may exacerbate conflict between health care teams and families concerning the withdrawal of mechanical ventilation.

It was never the intention of the US President's Commission, the LRCC, or any previous guideline for death determination to suggest that death was anything but a unitary phenomenon. Unfortunately, the bifurcated standard for death determination promotes confusion that negatively impacts stakeholders. Clarifying that death is defined in terms of brain function will help to resolve the apparent contradiction between the classical and neurologic signs of death in the way that the LRCC recommended over 30 years ago. In so doing, it will help to promote public and health care provider trust in medical practice and organ donation.

#### *Objective 2: to clarify how a brain-based definition of death is articulated*

The imprecision of terms integral to the definition of death has caused confusion and continues to stimulate controversy in the medical, bioethical, and legal literature.<sup>33,34,43</sup> Moreover, inconsistencies and imprecision in nomenclature may have implications for medical practice and organ donation.<sup>19</sup> Clarifying the meaning of the terms integral to the new operational definition of death will not by itself erase uncertainty, as resistance to evolving beyond historical heart-centered definitions may persist.<sup>5</sup> Additionally, an updated definition will not address the challenge of metaphysical or religious-based objection to the brain-based definition of death—a problem that pre-exists the proposed clarification.<sup>7,59</sup> Nonetheless, the updated Clinical Practice Guideline featured in this Special Issue seeks to articulate and clarify the meaning of the terms integral to the updated brain-based definition of death by addressing possible ambiguities.

#### IMPRECISION OF "BRAIN FUNCTION"

The updated death determination guideline seeks to clarify that, for the purposes of medicine, the terms "dead" or "deceased" denote an individual who has suffered permanent cessation of brain function, regardless of whether this is ascertained by DCC or DNC.<sup>2</sup> Previously accepted criteria for DNC in Canada held that death equates to the irreversible loss of the capacity for consciousness combined with the irreversible loss of all brain stem functions.<sup>8</sup> Yet the phrase "all brain stem functions," like the newly proposed term "brain function,"

is subject to interpretation, and controversy over similar legislative and guideline terminology in other jurisdictions has undermined confidence in DNC.<sup>13,43</sup> When defining death in terms of brain function there are several sources of ambiguity that demand clarification.

First, brain “function” is often confused with terms that do not necessarily indicate function. The activity of a cluster of neuronal cells, for example, does not necessarily constitute a function.<sup>13</sup> While the term has been defined as the “integration of a continuous neuronal input and output in the cerebrum and brainstem in response to physiologic stimuli,” confusion persists in the medical literature, wherein terms such as “flow” and “perfusion” are sometimes interchanged with “function” when the presence of neither flow nor perfusion necessarily entails function.<sup>14</sup> Clear elucidation of “function” and disambiguation of terms such as “activity,” “function,” “flow,” and “perfusion” are needed.<sup>C</sup>

Second, and relatedly, precise articulation of what is encompassed by “cessation of brain function” is required to address ongoing controversy.<sup>25,32–34,60</sup> The phrasing may suggest that death determination requires ascertaining the complete absence of any brain function. Yet DNC assesses only a subset of brain functions, and DCC does not directly assess brain function at all. Shewmon<sup>34,48</sup> and others have shown that, when maintained with somatic support, many individuals meeting the criteria for DNC retain hypothalamic–pituitary function, thermoregulatory control, and other neurohormonal endocrine functions.<sup>32,60</sup> Critics of brain death maintain that these individuals are by consequence alive,<sup>32</sup> while proponents contend that these functions are irrelevant to DNC.<sup>36,61</sup> Underlying these debates are distinctions between the fundamental functions of the brain to generate consciousness and brainstem reflexes (including the ability to breathe independently) *vs* unrelated functions such as hormonal control. The majority of practicing physicians are reluctant to acknowledge that the latter functions are salient to death determination because they play no role in consciousness or brainstem functions.<sup>13,17</sup> International guidelines support this stance,<sup>13</sup> and diagnostic tests for DNC consequently do not account for these neuroendocrine functions. In the same manner, tests of hormone release from the heart have no bearing in death determination following cardiac arrest.

Given the debates these issues have stimulated among medical professionals, authoritative clarification of which functions are encompassed by the phrase “cessation of

brain function” is needed. Further, the basis for which certain functions are ruled immaterial to DNC must be articulated to accommodate future discoveries of persisting noncritical functions that may arise. Clarification of which functions must be absent for DNC will serve to protect severely disabled patients from the premature withdrawal of life-sustaining measures, reassure health care professionals of the integrity of their diagnoses, maintain trust in deceased organ donation, and promote uniformity in practices for death determination.

#### IMPRECISION OF “IRREVERSIBLE” VS “PERMANENT”

Particularly with respect to death determination in the context of controlled organ donation after circulatory determination of death (cDCD), the meaning of the term “irreversible” in the formulation “irreversible cessation of cardiorespiratory function” has long been a source of controversy.<sup>16,62–64</sup> This terminology features in the UDDA<sup>5</sup> as well as previous Canadian guidelines for DCD.<sup>9</sup> For normative reasons, there is a general willingness to accept that loss of circulatory function is irreversible when a legally and ethically valid decision has been made not to restore what is, in many instances, a biologically reversible function.<sup>63</sup> Nevertheless, uneasiness remains in some quarters.<sup>16</sup> In the context of DCD, clarifying that all death is defined in terms of brain function will merely shift the focus of concern from the technically reversible loss of circulatory function to the technically reversible loss of brain function. The proliferation of resuscitative techniques suggests that this will be a perpetual source of discomfort unless this controversy is addressed.

Accordingly, the language in the updated death determination guideline seeks to align with established practice. By replacing the term “irreversible” with “permanent,” the operational, brain-based definition of death acknowledges that death can be determined when functions could conceivably be restored in some circumstances. While “irreversible” means *cannot be reversed under any circumstances*, “permanent” means *will not resume spontaneously and will not be reversed through intervention for normative reasons*.<sup>63</sup> In short, the updated definition of death explicitly clarifies that death can be determined when a legally and ethically valid decision has been made not to restore function even when this is technically feasible.

*Objective 3: To clarify the criteria for determining if the brain-based definition is met*

While Canadian guidelines for pediatric DCC were produced as recently as 2017,<sup>10</sup> guidelines for DNC and

<sup>C</sup> The challenge of being clear on the meaning of “function” is illustrated by the American Academy of Neurology’s Position Statement indicating that continued neuroendocrine function is not inconsistent with the whole brain standard of death, which is defined as the irreversible loss of “all brain function.”<sup>61</sup>

DCC in adults have not been revised since 2006.<sup>8,9</sup> Emerging technologies, an evolving evidence base, advances in ancillary testing techniques, and variability in practices for death determination suggest a need for up-to-date guidance on the means by which physicians ascertain that the criteria for a brain-based definition of death are met.

#### ACCOMMODATING EMERGING TECHNOLOGIES

Technological innovations have had significant implications for medicine's operational definition of death.<sup>20</sup> By a kind of technological counterexample, novel technologies such as mechanical ventilation challenged the legitimacy of corresponding criteria for death determination. Today, we face yet another clash of technology with operational concepts. The need for further refinements in the face of emerging technologies has become apparent in the context of cDCD, where interventions restoring circulation postmortem to improve organ viability are on the horizon.<sup>65</sup> Clarifying that the criteria used to determine death in cDCD entails the permanent loss of brain function will avoid the confusion and controversy that such interventions have generated.

To take an illustrative example, normothermic regional perfusion (NRP) is a novel application of extracorporeal membrane oxygenation (ECMO) employed postmortem on cDCD donors.<sup>66</sup> By recirculating oxygenated blood to target organs *in situ*, NRP may reverse ischemic damage sustained during the dying process.<sup>66–68</sup> When ECMO is deployed on a living patient for rescue, that patient is alive by virtue of persisting brain function. By contrast, in NRP, circulation is occluded below the neck to prevent intracranial circulation, reperfusion, and the consequent possibility of brain reanimation.<sup>66</sup> Because the donor's brain function has ceased permanently, the donor is properly understood to be deceased.<sup>69</sup> Nonetheless, previous criteria for DCC emphasizing cessation of circulation *simpliciter* do not reflect this.<sup>9</sup> For this reason, NRP and other interventions with the potential to restore circulation postmortem (e.g., intraoperative tidal ventilation in DCD lung donation) appear to challenge the Canadian criteria for death determination in cDCD.<sup>65</sup>

In cDCD, death is declared based on the permanent loss of circulatory function—a determination made in this context by observing a five-minute “hands-off” period following the loss of circulatory function.<sup>9</sup> By restoring circulation after that point, NRP would seem to invalidate the determination of death because circulation of oxygenated blood has resumed in the donor's body (though intracranial circulation is precluded). In actual fact, however, provided cessation of brain function has

occurred before restoration of extracranial circulation, an individual undergoing NRP would necessarily be dead because they have sustained permanent loss of brain function. Nonetheless, the previous disjunctive framework for death determination would require a separate neurologic exam before initiation of NRP because circulatory criteria would be invalidated by the resumption of extracranial circulation. Alternatively, updated cDCD guidelines to enable postmortem interventions restoring extracranial circulation could be pursued. Yet, both solutions would serve only to further complicate what is already a confusing picture. The existence of two seemingly disjunctive definitions of death (one based on cardiorespiratory function, and one based on neurologic function) is a source of distraction, underscoring the need to refine our operational definition of death in a manner that accurately describes the medical consensus on the biological basis of death: permanent cessation of brain function.

The challenge posed by NRP is only the most proximate example of how operational definitions of death should be designed to avoid potential confusion brought about by apparent alternate definitions of death as technology advances. By clarifying that all death is defined in terms of brain function, the updated death determination guideline seeks to accommodate advances by making explicit the central importance of brain function for biomedical understandings of death.<sup>65</sup>

#### VARIATION IN PRACTICES FOR DEATH DETERMINATION

Internationally, there is variation in practices for both DCC and DNC.<sup>25,52,53</sup> Just as it is confusing and inexpedient to have variable definitions of death, so is it confusing and inexpedient to have variation in practices for its determination. Variability of practices adversely impacts public and professional trust in death determination,<sup>15</sup> and prominent medical professional organizations are increasingly concerned that a resultant opposition to brain-based death determination will erode public confidence in medicine.<sup>31</sup>

The variability of practices for death determination internationally is also apparent within Canada.<sup>53,70</sup> This variability threatens public confidence and raises legal questions that must be addressed to reduce uncertainty and help shield physicians and hospitals from potential litigation.<sup>71</sup> Canadian legislation governing death determination in the context of organ donation generally mandates that death must be determined in accordance with “accepted medical practice.”<sup>19</sup> The updated guideline describing criteria and diagnostic tests for death determination will help to harmonize practices across Canada and avert legal challenges by ensuring the



community-derived, evidence-based, professional organization-endorsed reference standard for “accepted medical practice” is up to date.

#### NEED TO MINIMIZE THE RISK OF DIAGNOSTIC ERRORS

Clear guidance on the criteria and methods for death determination is equally important for minimizing the risk of diagnostic errors.<sup>71</sup> Although clinical diagnostic tests for DNC are widely agreed to be reliable when performed correctly,<sup>72</sup> recent legal cases in the USA highlight the need for greater certainty in the face of disputes among medical professionals regarding the determination of brain death.<sup>31</sup> Lack of uniformity in practices for death determination and nonadherence to best practice guidelines introduce a risk of diagnostic error (i.e., false positives), which threaten to undermine confidence in medicine.<sup>71</sup>

Minimum clinical criteria for death determination are outlined in existing guidelines, yet in some instances, confounders complicate assessment or interpretation.<sup>13</sup> Advances in ancillary testing techniques (e.g., computed tomography [CT] perfusion, CT angiography) have enabled physicians to assess brain blood flow with greater sensitivity.<sup>73</sup> Nevertheless, there remains variability in health care professionals’ understanding of the ancillary tests compatible with brain death determination.<sup>47,74</sup> Updated guidance on the use of ancillary testing is therefore warranted, especially considering that many techniques require enhanced expertise to perform and interpret results, that some are sensitive to phenomena that are not necessarily indicative of brain function (e.g., residual detection of minimal levels of brain blood flow that may be inadequate to restore brain function),<sup>14</sup> and that others have variable statistical precision.<sup>72</sup> To reduce the risk of false positives, protect the severely brain-injured, maintain public trust in medicine and deceased organ donation, and buttress physician confidence, best practices for the use and interpretation of ancillary tests must be delineated in up-to-date guidelines.

Quite apart from controversies over whether the criteria used to operationalize the permanent loss of brain function are in fact consonant with brain-based definitions of death,<sup>33</sup> it must be acknowledged that uncertainty remains concerning the accuracy of the means by which health care professionals ascertain whether these criteria are met. In the course of guideline development, the *A Brain-Based Definition of Death and Criteria for its Determination After Arrest of Neurologic or Circulatory Function in Canada* project identified numerous knowledge gaps relating to both DCC and DNC, all of which are outlined elsewhere in this Special Issue of the

*Journal*.<sup>75</sup> As a result, many of the guideline’s recommendations are based on low to moderate certainty of evidence. Further research is therefore required to buttress stakeholder confidence that diagnostic tests accurately identify the permanent loss of brain function in all instances and for all populations.

#### Conclusion

Previous definitions of death and criteria for its determination have been instrumental for medical practice and organ donation. Ongoing scientific discovery, corresponding changes in medical practice, as well as legal and ethical challenges have arisen that compel a comprehensive update. A unified brain-based definition of death and criteria for its determination in a Canadian medical guideline will help address this evolution by clarifying that all death is defined in terms of brain function.

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