

Legal Foundations for the Neurological Determination of Death

#### **Acknowledgements**

The Planning Committee for the Forum on Severe Brain Injury to Neurological Determination of Death (April 9-11, 2003) commissioned "Legal Foundations for the Neurological Determination of Death" as an introduction to the legal considerations related to formalizing and recording the method for the neurological determination of death. This piece is abstracted from a longer document prepared by Kathryn Burke, BA (Hon), MA, Burke & Associates Inc. It is intended as a background document to support discussion, not as a comprehensive scholarly legal commentary.

The views in the paper do not reflect the official policy of the Canadian Council for Donation and Transplantation and are not intended for publication in their current format.

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# **Contents**

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### **Introduction and Preamble**

This paper provides an overview of the status of legislation in Canada and selected jurisdictions on the determination of death. It does not investigate the advantages and disadvantages of embodying in law a definition of death and neurological determination of death. Debate about what items should be included (or excluded) from regulation and statute is a complex matter.

This paper examines the status of legislation on the definition of death and its determination in Canada, select Commonwealth nations and the United States. This paper is predicated upon the assumption that the definition of death is irreversible cessation of all functions of the entire brain including the brainstem and that the validity of this definition is incontrovertible.

Discussion should ultimately occur about whether there is merit in pursuing a legislative option in Canada for a neurological definition of death and its determination. Information contained in this paper may inform that discussion.

This paper should be regarded as a working draft with no intent to pursue publication in its current format.

## **Guiding Questions**

Some key questions guide the examination of the statutory definition of death and its neurological determination:

- Is "death" defined in law?
- Do provisions exist in legislation about the determination of death for the purposes of post-mortem donation of human tissue for transplantation?
- Does law outline the actual mechanisms (i.e., tests) to be used in the determination of death?

### **Canadian Legislation**

In Canada, health care is primarily the jurisdictional responsibility of the provinces and territories. Consequently, legislative provisions for the determination of death must be considered at a provincial and territorial level. Appendix One contains a summary of the relevant legislation by province and territory.

### Definition of death in law

With the exceptions of the laws in Manitoba and Prince Edward Island, Canadian provincial and territorial legislation does not contain a statutory definition of death.

In Manitoba, death is defined in the Vital Statistics Act, and the definition is referenced in Section 8(1) of the Human Tissue Gift Act.<sup>2</sup> The Vital Statistics Act employs a whole-brain concept of neurological death: "For all purposes within the legislative competence

<sup>1</sup> This report has been commissioned by the Canadian Council for Donation and Transplantation as preparatory material for "Severe Brain Injury to Neurological Determination of Death—A Canadian Forum".

<sup>2</sup> The Human Tissue Gift Act, Province of Manitoba, Chapter H180, Section 8(2).

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".<sup>3</sup>

Prince Edward Island legislation, in the definitions section, states, "... 'death' includes brain death as determined by generally medically accepted criteria".<sup>4</sup>

Canadian law contains examples of judicial precedent that take on the power of law. The Manitoba Court of Appeal heard a notable case in 1976. An accused assailant claimed that his victim (who sustained a skull fracture) died because of the removal of his kidneys and not because of the assailant's actions. The victim, who had ceased breathing after he sustained the injury, had cardiac and pulmonary functions restored by emergency medical personnel. Following declaration of death, his kidneys were removed for transplantation. The assailant claimed the removal of the kidneys was the sole cause of death with a defence of "*novus actus interveniens*". The guilty verdict of murder was upheld, providing implicit recognition of a brain death concept.<sup>5</sup>

There is no definition of death in federal law, although the Criminal Code contains provision for imprisonment if a person improperly or indecently interferes with or offers an indignity to a dead human body or human remains, whether buried or not.<sup>6</sup>

#### Determination of death

With the exception of Quebec, New Brunswick, the Northwest Territories and Nunavut,<sup>7</sup> all provinces have legislation that includes provision for the determination of death for the purposes of post-mortem transplantation. Paraphrased, determination of death must be made by two physicians in accordance with accepted medical practice. The physicians making the determination of death must not have any association with the proposed recipient of the organ or tissue and cannot participate in the transplant process. Some provinces waive this latter provision with respect to the removal of eyes for the purposes of corneal transplantation.

#### Mechanisms to be used in the determination of death

Provincial and territorial legislation does not outline what is meant by "accepted medical practice" or the tests or mechanisms that should be employed to determine death.

#### Protection from liability

Legislation in 9 of the 13 provinces and territories contains provisions for immunity from civil proceedings providing the party acted in "good faith and without negligence." Provisions in Ontario have dropped the "without negligence" component that effectively makes the protection much stronger.

<sup>3</sup> Vital Statistic Act, Section 2, Province of Manitoba, C.C.S.M. c. V60

<sup>4</sup> Human Tissue Donation Act, Section 1(b) 1995. In 1991, Prince Edward Island adopted the Uniform Human Tissue Donation Act.

<sup>5</sup>*R. v. Kitchling and Adams* (1976) 6 W.W.R. 697 (Manitoba Court of Appeal), as reported in Law Reform Commission of Canada, Working Paper 23, *Criteria for the determination of death.* 1979: 23-24.

<sup>6</sup> Criminal Code. R.S., c.C-34, s. 182(b).

<sup>7</sup> The Nunavut Act, S.C. 1993, c.28 as amended brought Nunavut into being April 1, 1999 (s.3), and provides, at s.29, that the ordinances of the present Northwest Territories and "the laws made under them" effective March 31, 1999, will be duplicated for Nunavut. Therefore, Nunavut has exactly the same legislation governing organ and tissue donation and transplantation as the Northwest Territories.

#### Uniform Human Tissue Donation Act

In 1990, the Uniform Law Conference of Canada, a group dedicated to harmonizing statutes in provinces and territories across Canada, developed the Human Tissue Gift Act. With the exception of Prince Edward Island, the Uniform Act was not enacted in any province or territory.

The Human Tissue Donation Act contains a definition of death (as outlined for Prince Edward Island, above) and provisions for determination of death that are consistent with those employed in legislation across the country.

#### Summary of Canadian legislation

Table One contains a summary comparison of the major features of legislation in Canada by province and territory.

### Table One: Summary Comparison of Canadian Legislation by Province and Territory

Legislative Provisions	British Columbia	Alberta	Saskatchewan	Manitoba	Ontario	Quehec	New Brunswick	Nova Scotia	Prince Edward Island	Newfoundland & Labrador	Yukon	Nunavut <sup>a</sup>	Northwest Territories
Human Tissue Gift Act legislation <sup>9</sup>	•	•	•	•	•	O <sup>10</sup>	•	•	•	•	•	•	•
Statutory definition of death:													
Brain death criterion				•					•				
Cardiopulmonary criterion													
Provisions for 2 independent physicians to declare death	•	•	•	•	•			•	•	•	•		
Qualifications of physicians declaring death													
Prohibitions for declaring physicians to be involved in transplant or transplant patient	•	•	•	•	•			•	•	•	•		
Waiver of physician independence for removal of eyes or non-perfusible tissue	•	•	•	•	•			•	•	•	•		
Fact of death determined in accordance with <i>accepted</i> medical practices	•	•	•	•	•			•	•	•	•		
Protection from criminal prosecution or civil liability	•	•	•	•	•			•	•	•	•		
Adoption of Uniform Human Tissue Donation Act, 1990									•				

<sup>8</sup> The Nunavut Act, S.C. 1993, c.28 as amended brought Nunavut into being April 1, 1999 (s.3), and provides, at s.29, that the ordinances of the present Northwest Territories and "the laws made under them" effective March 31, 1999, will be duplicated for Nunavut.

<sup>9</sup> Comprehensive legislation that provides a legislative framework for organ and tissue donation and transplantation activities in the province or territory. 10 Quebec does not have a Human Tissue Gift Act *per se*, though it has amended its civil code to include general provisions on the living donation of, removal of and transplantation of organs and tissues.

### **Legislation in Selected Commonwealth Nations**

Canada's status as a Commonwealth nation and fact of similar jurisprudence prompted a review of legislation in the United Kingdom, New Zealand and Australia.

#### Definition of death in law

There is no statutory definition of death in the United Kingdom. The common law of England and Northern Ireland has adopted criteria for the neurological determination of death from standards generated by the Conference of Royal Colleges<sup>11</sup> in 1976 and 1979 (subsequently reviewed in 1995).

There is no statutory definition of death in New Zealand. New Zealand uses the standards established by the Australian and New Zealand Intensive Care Society (ANZICS),<sup>12</sup> which are consistent with the criteria for the neurological determination of death outlined by the Royal Colleges in the United Kingdom.

Australia is a nation comprised of several states and territories. Except in Western Australia, death is legally defined in statute as "when there is an irreversible cessation of circulation of blood in the body of the person, or irreversible cessation of all functions of the brain of the person."<sup>13,14,15,16,17,18</sup>

Western Australia does not have a statutory definition of death, although it does have legislation governing organ and tissue donation and transplantation that makes reference to the cessation of brain function in clauses associated with the determination of death. Australia's clinicians use the ANZICS standards for neurological determination of death.

#### **Determination of death**

Australian law stipulates that two medical practitioners must make neurological determination of death when respiration is being maintained by separate means. This condition is also stipulated in the New Zealand Code of Practice.<sup>19</sup>

#### Qualifications of physicians determining death

Australian state and territorial legislation includes provisions that outline the qualifications of physicians making the neurological determination of death. For example, in the Northern Territories, such determination can be made only by a physician who has practised for five years or more. One of the two physicians must be a specialist, further defined as "an anesthetist, a general surgeon, neurologist, neurosurgeon or physician".<sup>20</sup> Similar provisions exist in the Australian Capital Territory. A minimum of five years in practice is required, and one of the two physicians must be a specialist neurologist or neurosurgeon or have other defined qualifications. Provisions across the balance of Australia are similar.

<sup>11</sup> Ibid, 9.

<sup>12</sup> Australian and New Zealand Intensive Care Society (ANZICS). *Recommendations on brain death and organ donation*, 2nd edition. Carlton, VIC, Australia: ANZICS, 23 March 1998.

<sup>13</sup> Transplantation and Anatomy Ordinance 1978, s.45. Australian Capital Territory.

<sup>14</sup> Human Tissue Transplant Act 1979 and Human Tissue Amendment Act 1989, s.23. Northern Territory (Australia).

<sup>15</sup> Transplantation and Anatomy Act 1979-1984, s.45. Queensland.

<sup>16</sup> Human Tissue Act 1982 and Human Tissue Amendment Act 1987, s.118. Victoria.

<sup>17</sup> Human Tissue Act 1983, s.33. New South Wales.

<sup>18</sup> Human Tissue Act 1985 and Human Tissue Amendment Act 1987, s.27A. Tasmania.

<sup>19</sup> ANZICS op cit., 9.

<sup>20</sup> Human Tissue Transplant Act 1979 and Human Tissue Amendment Act 1989, s.21. Northern Territory (Australia).

#### Mechanisms to be used in the determination of death

Australian state and territorial legislation does not define the tests and strategies to be used to determine death. Legislation indicates that physicians who are determining death are to carry out a "clinical examination", although the exact nature of the clinical examination is not specified. It is noteworthy that the specifics of the clinical examination are outlined in the ANZICS standards.

#### Protection from liability

With the exception of actions associated with negligence, Australian legislation provides protection for an individual who is fully compliant with legislation.

### **Legislation in the United States**

#### Definition of death in law

Forty-two states and protectorates in the United States have adopted the Uniform Determination of Death Act (UDDA) 1980 (see Table Two). The UDDA defines death in the following manner: "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brainstem, is dead. A determination of death must be made in accordance with accepted medical standards." <sup>21</sup>

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Adopted		Not Adopted
Alabama	Nevada	Florida
Alaska	New Hampshire	Hawaii
Arizona	New Mexico	Illinois
Arkansas	New York ** (substantially similar)	Iowa
California	North Carolina	Kentucky
Colorado	North Dakota	Louisiana
Connecticut	Ohio	Massachusetts
Delaware	Oklahoma	Texas
District of Columbia	Oregon Pennsylvania	Virginia
Georgia	Puerto Rico	
Idaho	Rhode Island	
Indiana	South Carolina	
Kansas	South Dakota	
Maine	Tennessee	
Maryland	Utah	
Michigan	Vermont	
Minnesota	Virgin Islands	
Mississippi	Washington ** (judicial adoption)	
Missouri	West Virginia	
Montana	Wisconsin	
Nebraska	Wyoming	

# Table Two: Adoption of Uniform Determination of Death Act by U.S. states and protectorates

The UDDA provides only one element of the legislative framework for donation and transplantation; namely, it establishes a statutory definition of death. The legislative

<sup>21</sup> Uniform Determination of Death Act 1980, s.1. National Conference of Commissioners of Uniform State Laws. Approved by the American Medical Association, 19 October 1980, and the American Bar Association, 10 February 1981.

framework for states and protectorates vary; representative examples are provided in Appendix Two.

Among the states that have not adopted the UDDA (except Massachusetts and Washington, which have judicial acceptance of brain death), state legislation does provide for statutory definition of death based on, at minimum, the irreversible cessation of brain function. Cardiopulmonary function is also identified as a criterion for death in most, but not all, of the states that have not adopted the UDDA.

#### Mechanisms to be used in the determination of death

States that have adopted the UDDA indicate that such determination will be made in accordance with accepted medical standards.

There is variation in the legislation for states that have not adopted the UDDA. *In toto,* the non-adoptive states are more definitive about the mechanisms to be used to determine death. With the exception of Texas, all non-UDDA states have requirements for two physicians to make the determination of death for the purposes of post-mortem transplantation. Three specify the qualifications of the physicians who are eligible to make this determination. Delaware is the only state of those that have adopted the UDDA that makes provision in law about the qualifications of physicians determining brain death. New Jersey has provisions in law for regulations to specify the qualifications of physicians.

The absence of legislative provisions does not preclude adoption of comprehensive standards in the determination of death. No attempt was made to determine the use of standards throughout the United States.

#### Protection from liability

Seven states have provisions that provide protection from civil or criminal proceedings for individuals complying with legislation related to donation and transplantation.

#### **Religious considerations**

New Jersey legislation indicates that death must not be declared in violation of an individual's religious beliefs. Law indicates that if a physician has reason to believe that a neurological determination of death would violate a person's religious beliefs, then the determination of death is to be made based on cardiorespiratory criteria.<sup>22</sup> Similar provisions exist for the State of New York.

### **Issues and Observations**

#### The adequacy of current definitions of death

Bernat<sup>23</sup> criticizes the UDDA definition of death. He argues that the UDDA definition codifies the tests for the neurological determination of death rather than defining death as a single, whole-brain criterion with two tests. The Law Reform Commission of Canada,<sup>24</sup> in a paper pre-dating the UDDA, argues that whole-brain death is a sign of death. The implication of both is that death should not be defined by the methods used for its determination.

<sup>22</sup> New Jersey 26:6A-5, L. 1991, c.90, s.5.

<sup>23</sup> Bernat, JL. Ethical issues in neurology, 2nd edition. Boston.Butterworth Heinemann; 2002: 254.

<sup>24</sup> Law Reform Commission of Canada, op cit., 57.

The Law Reform Commission of Canada also warns about the danger of describing different "types" of death, such as may emerge from a focus on the cessation of circulatory or respiratory functions or the irreversible cessation of functions of the entire brain. Both are "symptoms" of death—essentially the point made by Bernat.

Bernat, with his colleagues C.M. Culvert and B. Gert,<sup>25</sup> proposed the following as a replacement to the UDDA statutory definition of death: "An individual who has sustained irreversible cessation of all functions of the entire brain, including the brainstem, is dead. In the absence of artificial means of cardiopulmonary support, death may be determined by the prolonged absence of spontaneous circulatory and respiratory functions. In the presence of artificial means of cardiopulmonary support, death must be determined by tests of brain functions. In both situations, the determination of death must be made in accordance with accepted medical standards".

The Law Reform Commission of Canada proposed a similar definition of death, which they recommended should be uniformly adopted in all provinces and territories in Canada:

A person is dead when an irreversible cessation of all that person's brain functions has occurred.

The cessation of brain functions can be determined by the prolonged absence of spontaneous cardiac and respiratory functions.

When the determination of the absence of cardiac and respiratory functions is made impossible by the use of artificial means of support, the cessation of the brain functions may be determined by any means recognized by the ordinary standards of current medical practice.<sup>26</sup>

Canada differs from Australia and the United States in that provincial and territorial legislation does not include a statutory definition of death (with the exceptions of Manitoba and Prince Edward Island). An important question is whether the absence of statutory definition is meaningful.

The Law Reform Commission of Canada provides compelling arguments throughout its report for the adoption of a statutory definition of death. The Commission argues that something as fundamental as death should be embodied in law (and not just judicial precedent) and that a legal definition of death has implications far beyond the field of medicine and organ transplantation (e.g., criminal and estate law).<sup>27</sup>

<sup>25</sup> Bernat JL, Culver CM, Gert B. On the definition and criterion of death. *Ann Intern Med.* Mar;(94)3;1981:393; and Bernat, JL, Culver CM, Gert B. Defining death: which way? *Hastings Centre Rep* 12(2);1982:8, as reported in Bernat, *op cit.*, 2002: 255.

<sup>26</sup> Law Reform Commission of Canada, op cit., 58-59.

<sup>27</sup> The Law Reform Commission of Canada, in its Working Paper on Criteria for the Determination of Death, identifies proposed approaches to the definition of death, including (1) determination being solely the domain of physicians, (2) determination being based on judicial precedent and (3) determination by legislation. This discourse provides interesting background information and should be reviewed by readers wishing to explore this topic in more detail. For the purposes of this paper, the detailed arguments by the Law Reform Commission will not be repeated, with the view that those seeking more information about the advantages and disadvantages of the different approaches will refer to the document directly.

#### Protection from prosecution

The Law Reform Commission of Canada makes the argument that because of the absence of a legal definition of death in Canada, physicians engaged in either the declaration of brain death or the subsequent removal of a vital organ for the purposes of transplantation may risk (of feel that they are at risk of) prosecution. The analogy of the sword of Damocles is made, with the implication that this threat may negatively affect their involvement with transplantation.

Provisions exist in legislation in nine provinces and territories in Canada that provide immunity from civil proceedings. It is unclear whether physicians in Canada feel that the absence of a legal definition of death may result in their potential demise by the sword of Damocles. However, it is clear that there is a lack of legislative precision on this matter. While such matters can be determined by judicial precedent, the wisdom of a reactive versus proactive approach must be debated. The Law Reform Commission of Canada is clearly in favour of a more proactive approach.

#### The impact of "soft law"

Consensus standards and medical guidelines are relevant to the ongoing discussion about the legal framework for determination of death and post-mortem donation of human tissue for transplant for two reasons. First, in the absence of comprehensive legislation (or key provisions in legislation), guidelines may be used as tools to establish judicial precedent. Second, a review of legislation in Canada, the United States and Australia identifies that even with comprehensive legal frameworks, reference is made to such conditions as "accepted medical practices". Specifically, technical details like tests to be used to make the determination of death are not and, it can be argued, should not be embodied in law. They are the domain of standards or guidelines. <sup>28</sup>

Campbell and Glass<sup>29</sup> discuss the concept of "soft law" in a recent paper that describes the legal importance of medical policies and guidelines. Soft laws have their roots in the medieval period, when self-regulating professions such as Medicine and Law developed normative standards of practice.<sup>30</sup> In the absence of central governments, self-regulating professions were subject only to the scrutiny of their peers. In modern times, the state has become the central authority for regulating professional groups, although certain professions, such as Medicine, have retained large measures of self-regulation. Many self-regulating professional associations support policies against legislative intervention. The development of practice guidelines that establish normative standards of conduct is an important responsibility of a self-regulating profession.

Campbell and Glass make the argument that when the law is unclear or incomplete on matters of professional responsibility, the court refers to non-legal professional instruments such as practice standards to make legal findings. This practice transforms the professional standard into "soft law".<sup>31</sup> The chance for the professional standard to take on the status of "soft law" depends on a variety of factors—normative status or professional acceptance and use of standards, currency, evidence in support of the standards and consideration of ethical issues, to name a few.

<sup>28</sup> Appendix Three contains descriptions of key terms such as "standards", "guidelines" and legal phrases that are relevant to this discussion.

<sup>29</sup> Campbell, A., and Glass, K.C. The legal status of clinical and ethics policies, codes, and guidelines in medical practice and research. *McGill L.J.* 46 (2001) 473.

<sup>30</sup> Ibid, 475-76.

<sup>31</sup> Ibid, 482.

The argument is made that standards can exhort certain behaviour but do not enforce that behaviour. This argument is in contrast to the provisions of law, backed up by sanction that represents society's interests. Campbell and Glass argue that standards and guidelines are important in assisting the court with questions of professional responsibility<sup>32</sup> but that they do not replace laws.

The implication is that there are some matters that should and must be addressed in law to best represent society's interests—to be developed in a democratic and transparent manner to address the prevailing wishes and needs of a country's citizens. It is also clear that the law is cumbersome and often less flexible in providing detailed guidance on matters of clinical practice, particularly if the field is one characterized by rapid change.

### **Concluding Comments and Questions**

The material in the preceding sections attempts to summarize key features about the legal definition of death in Canada, selected Commonwealth countries and the United States. It also attempts to summarize key issues associated with the determination of death for the purposes of the post-mortem transplantation of human tissue.

The analysis suggests that Canada does not universally embrace a statutory definition for the neurological determination of death. However, Canadian legislation does provide a framework for donation and transplantation activities in the various provinces and territories and ensures that the determination of death is independent. Legislation values the importance of ensuring that physicians are free from any conflicts when determining the death of an individual for the purposes of the post-mortem donation of human tissues. However, unlike other jurisdictions, Canada does not identify the qualifications of the physicians making the determination of death.

The legal foundation for donation and transplantation in Canada appears to have worked well, and individuals (and organizations) favouring a minimalist approach might argue that no changes are required. The current Canadian judicial system also provides the opportunity for well-developed and supported standards to take on the power of "soft law".

Others may argue that Canada errs on the side of having too little legislation, particularly with respect to a legal definition of death. The opportunity to embody in law important issues such as the definition of death and the qualifications of those who may make its determination for the purposes of post-mortem determination of human organs—and to debate such issues in an open and transparent process—has merit in a democratic society.

# Appendix One Summary of Relevant Clauses in Canadian Provincial and Territorial Legislation

Province/Territory	Relevant Clauses in Legislation	Act/Date
British Columbia	Determination of death	Human Tissue Gift Act,
	7(1) For a post mortem transplant, the fact of death must be determined by at least 2 medical practitioners in	R.S.B.C. 1996, C.211
	accordance with accepted medical practice.	
	(2) A medical practitioner who has had any association with the proposed recipient of the post mortem transplant	
	that might influence the medical practitioner's judgment must not take any part in the determination of the fact of	
	death of the donor.	
	(3) A medical practitioner who took any part in the determination of the fact of death of the donor must not	
	participate in any way in the transplant procedures.	
	(4) Nothing in this section in any way applies to a medical practitioner in the removal of eyes for cornea transplants.	
Alberta	Determination of death	Human Tissue Gift Act, R.S.A.
	7(1) For the purposes of a post-mortem transplant, the fact of death must be determined by at least 2 physicians in	1980, C.H-15, c.H-12, s.7
	accordance with accepted medical practice.	
	(2) No physician who has had any association with the proposed recipient that might influence that physician's	
	judgment shall take any part in the determination of the fact of death of the donor.	
	(3) No physician who took any part in the determination of the fact of death of the donor shall participate in any way	
	in the transplant procedures.	
Saskatchewan	(4) Nothing in this section in any way affects a physician in the removal of eyes for cornea transplants. Determination of death	Human Tissue Gift Act, R.S.S.
Saskatchewan	8(1) For the purposes of a post-mortem transplant, the fact of death shall be determined by at least 2 physicians in	1978, C.H-15, c.H-15, s.8
	accordance with accepted medical practice.	1970, C.H-15, C.H-15, S.O
	Prohibition	
	(2) No physician who has had any association with the proposed recipient that might influence his judgment shall	
	take any part in the determination of the fact of death of the donor.	
	Same	
	(3) No physician who took any part in the determination of the fact of death of the donor shall participate in any way	
	in the transplant procedures.	
	Exception	
	(4) Nothing in this section in any way affects a physician in the removal of eyes for cornea transplants.	
Manitoba	Determination of death	Human Tissue Act, S.M. 1992,
	8(1) Any determination of the occurrence of brain death within the meaning of The Vital Statistics Act, with	c.33, s.29.
	circulation still intact, that may be necessary for the purposes of a successful transplant of tissue pursuant to this	
	Act shall be made by at least two physicians and subject to subsections (2) and (3).	
	Independence of physicians	
	8(2) A physician who has or has had an association with a proposed recipient of tissue by way of transplant	
	pursuant to this Act, where the association is or was of such a nature that it is likely to influence the judgment of the	
	physician, shall not participate in the making of a determination under subsection (1) of the death of the person from	
	whose body the tissue is to be removed.	

Province/Territory	Relevant Clauses in Legislation	Act/Date
	Participation in transplant prohibited 8(3) A physician who participates in (a) a determination of death under subsection (1); or (b) the withdrawal or withholding of life-prolonging medical treatment in accordance with a health care directive made under <i>The Health Care Directives Act</i> ; In respect of a person from whose body tissue is to be removed for a proposed transplant shall not participate in the transplant operation.	
N.B. This clause is not in the Human Tissue Act but the Vital Statistics Act.	When death occurs 2 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.	The Vital Statistics Act, C.C.S.M., c.V60
Ontario	<ul> <li>Determination of death 7(1) For the purposes of a <i>post mortem</i> transplant, the fact of death shall be determined by at least two physicians in accordance with accepted medical practice. R.S.O. 1990, c. H.20, s.7(1). Prohibition (2) No physician who has had any association with the proposed recipient that might influence the physician's judgment shall take any part in the determination of the fact of death of the donor. R.S.O. 1990, c. H.20, s.7(2); 2000, c.39, s.3. Idem (3) No physician who took any part in the determination of the fact of death of the donor shall participate in any way in the transplant procedures. R.S.O. 1990, c.H.20, s.7(3). Exception (4) Nothing in this section in any way affects a physician in the removal of eyes for cornea transplants. R.S.O. 1990, c.H.20, s.7(4).</li> </ul>	Trillium Gift of Life Network Act, R.S.O. 1990, c.H.20
Quebec	No specific legislation, although there are civil statutes that contain definitions and miscellaneous issues associated with the donation of transplanted human tissue.	
New Brunswick	No clause in Act on determination of death	Human Tissue Act, C.H-12
Nova Scotia	Determination of fact of death         8(1) 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.         Conflict of interest         (2) No physician, who has had any association with the proposed recipient that might influence his judgment, shall take any part in the determination of the fact of death of the donor.         Prohibition on participation in transplant         (3) No physician, who took any part in the determination of the fact of death of the donor, shall participate in any way in the transplant procedures.         Exception respecting cornea transplant	Human Tissue Gift Act, C.215 of the Revised Statutes, 1989, Amended 1991, c.13
	(4) Nothing in this Section in any way affects a physician in the removal of eyes for cornea transplants. R.S., c.215, s.8.	

Province/Territory	Relevant Clauses in Legislation	Act/Date
Prince Edward Island	Definitions         1(b) "death" includes brain death as determined by generally accepted medical criteria;         Determination of death         11(1) The fact of death of a donor of tissue shall be determined by at least two physicians in accordance with accepted medical practice.         Independence of physician         (2) No physician who has had any association with the proposed recipient of tissue shall take any part in the determination of the fact of death of the donor of that tissue.         Idem         (3) No physician who took any part in the determination of the fact of death of the donor of tissue shall participate in any way in the transplant of that tissue.         Application of subsection (1)         (4) The requirement of subsection (1) for the fact of death to be determined by at least two physicians does not apply where         (a) only non-perfusible tissue is to be removed from the donor; and         (b) the fact of death of the donor has been determined by a physician following cessation of the donor's heart function.         Application of Subsections (2) and (3)         (5) Subsections (2) and (3) do not apply to a physician in respect of non-perfusible tissue.	Human Tissue Donation Act, C.1-12.1, c.32, s.11; 1995, c.20, s.2
Newfoundland and Labrador	<ul> <li>Determination of death</li> <li>9(1) For the purpose of an after death transplant, the fact of death shall be determined by at least 2 legally qualified medical practitioners in accordance with accepted medical practice.</li> <li>(2) A legally qualified medical practitioner</li> <li>(a) who takes part in the determination of the fact of death of the donor; or</li> <li>(b) who has had an association with the proposed recipient that might influence his or her judgment shall not participate in the transplant procedure.</li> <li>(3) Nothing in this section affects a legally qualified medical practitioner in the removal of eyes for cornea transplants.</li> </ul>	Human Tissue Act, R.S.N.L. 1999, C.H-15, Amended: C.H-15, An Act Respecting Human Tissue and the Disposition of Human Bodies, 1971, No66 s.10
Yukon	Determining death         7(1) For the purposes of a post-mortem transplant, the fact of death shall be determined by at least two medical practitioners in accordance with accepted medical practice.         (2) No medical practitioner who has had any association with the proposed recipient that might influence his judgment shall take any part in the determination of the fact of death of the donor.         (3) No medical practitioner who took any part in the determination of the fact of death of the donor shall participate in any way in the transplant procedures.         (4) Nothing in this section in any way affects a medical practitioner in the removal of eyes for a cornea transplant.	Human Tissue Gift Act, R.S.Y. 1986, c.89

Province/Territory	Relevant Clauses in Legislation	Act/Date
Nunavut	The Nunavut Act, S.C. 1993, c.28 as amended brought Nunavut into being April 1, 1999 (s.3), and provides, at s.29, that the ordinances of the present Northwest Territories and "the laws made under them" effective March 31, 1999, will be duplicated for Nunavut.	
	To accommodate modifications of N.W.T. law, which are required to be in force April 1, 1999, ss. 29 and 76.05 of the Nunavut Act were amended to allow the government of the N.W.T. to pass certain kinds of legislation on Nunavut's behalf. These powers were exercised in packages of "Division Legislation", which received Royal Assent December 9, 1998 (6th Session of the 13th Legislative Assembly), and March 29th, 1999 (7th Session of the 13th Legislative Assembly). This legislation is available in the Courthouse library.	
	A revision of Nunavut statutes as at April 1, 1999, is expected to be complete some time in the 2001-2002 fiscal year.	
Northwest Territories	No clause in Act on determination of death	Human Tissue Act as referenced in the Consolidation of Human Tissue Act, R.S.N.W.T. 1988, cH-6
Human Tissue Donation	Definitions	Human Tissue Donation Act
Act (Uniform Model Act)	1. "Death" includes brain death as determined by generally accepted medical criteria; ("mort") Determination of death	April 1990
	11(1) The fact of death of a donor of tissue shall be determined by at least 2 physicians in accordance with accepted medical practice.	
	(2) No physician who has had an association with the proposed recipient of tissue shall take any part in the determination of the fact of death of the donor of that tissue.	
	(3) No physician who took any part in the determination of the fact of death of the donor of tissue shall participate in any way in the transplant of that tissue.	
	(4) Subsections (2) and (3) do not apply to a physician in the removal of eyes for cornea transplants.	

# Appendix Two Representative Examples of American Legislation (including the UDDA, a state that has adopted the UDDA, a state that has not adopted the UDDA and the specific example of New Jersey)

Uniform Determination of	Determination of Death.
Death Act	An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all
Approved by the American	functions of the entire brain, including the brainstem, is dead. A determination of death must be made in accordance with accepted
Medical Association: 19 October	medical standards.
1980	
Approved by the American Bar	
Association: 10 February 1981	
Alabama (adopted UDDA)	Section 22-31-1
	Standards and procedures for determination of death generally. (a) A person is considered medically and legally dead if, in the opinion of
	a medical doctor licensed in Alabama, based on usual and customary standards of medical practice, in the community, there is no
	spontaneous respiratory or cardiac function and there is no expectation of recovery of spontaneous respiratory or cardiac function. (b) In
	the case when respiratory and cardiac function are maintained by artificial means, a person is considered medically and legally dead if, in
	the opinion of a medical doctor licensed in Alabama, based on usual and customary standards of medical practice in the community for
	the determination by objective neurological testing of total and irreversible cessation of brain function, there is total and irreversible
	cessation of brain function. Death may be pronounced in this circumstance before artificial means of maintaining respiratory and cardiac
	function are terminated. In the case described in this subsection, there shall be independent confirmation of the death by another medical
	doctor licensed in Alabama. (Acts 1979, No. 79-165, p. 276, §1.)
	Section 22-31-2
	Use of other methods. Nothing in this chapter shall prohibit a physician from using other procedures based on usual and customary
	standards of medical practice for determining death as the exclusive basis for pronouncing a person dead. (Acts 1979, No. 79-165, p. 276,
	§2.)
	Section 22-31-3
	Procedure where part of body to be used for transplantation. (a) When a part of a donor is proposed to be used for transplantation
	pursuant to Article 3 of Chapter 19 of this title and the death of the donor is determined as set forth in Section 22-31-1, there shall be an
	independent confirmation of the death by another medical doctor licensed in Alabama. Neither the physician making the determination of
	death nor the physician making the independent confirmation shall participate in the procedures for removing or transplanting a part. (b)
	When a part of a donor is proposed to be used for transplantation pursuant to Article 3 of Chapter 19 of this title and the death of the donor
	is determined as set forth in Section 22-31-1, complete patient medical records shall be kept, maintained and preserved. (Acts 1979, No.
	79-165, p. 276, §§3, 4.)
	Section 22-31-4
	Liability for acts. A person who acts in accordance with the terms of this chapter is not liable for damages in any civil action or subject to
	prosecution in any criminal proceeding for his act. (Acts 1979, No. 79-165, p. 276, §5.)

Hawaii (not adopted UDDA)	<b>§327C-1</b> Determination of death. (a) Except as provided in subsection (b), a person shall be considered dead if, in the announced opinion of a physician licensed under chapter 460, physician excepted from licensure by section 453-2(b)(3), or registered nurse licensed under chapter 457, based on ordinary standards of current medical practice, the person has experienced irreversible cessation of spontaneous respiratory and circulatory functions. Death will have occurred at the time when the irreversible cessation of the functions first coincided. (b) In the event that artificial means of support preclude a determination that respiratory and circulatory functions. Death will, have occurred at the time when the irreversible cessation of a physician licensed under part I of chapter 453, attending physician licensed under part I of chapter 453, attending physician licensed under part I of chapter 453, consulting physician and surgeon licensed under chapter 460, or attending physician and surgeon licensed under chapter 453, consulting physician and surgeon licensed under chapter 450, consulting physician excepted from licensure by section 453-2(b)(3), and of a consulting physician licensed under part I of chapter 450, or consulting physician excepted from licensure by section 453-2(b)(3), and of a consulting physician licensed under the tari, including the brainstem, first occurred. Death shall be pronounced before artificial means of support are withdrawn and before any vital organ is removed for purposes of transplantation. (c) When a part of a donor is used for direct organ transplantation under chapter 327, and the donor's death is established by determination by be made under subsection (b). The determination of death in all other cases shall be made under subsection (b). The determination of death in all other cases dail be made under subsection (b). The director of health may convene in every odd-numbered year, a committee which shall be composed of representatives of appropriate general and specialized medica
New Jersey	<ul> <li>26:6A-1. Short title; declarations in accord with act a. This act shall be known and may be cited as the "New Jersey Declaration of Death Act." b. The death of an individual shall be declared in accordance with the provisions of this act. L.1991,c.90,s.1.</li> <li>26:6A-2. Declaration of death based on cardio-respiratory criteria An individual who has sustained irreversible cessation of all circulatory and respiratory functions, as determined in accordance with currently accepted medical standards, shall be declared dead. L.1991,c.90,s.2.</li> <li>26:6A-3. Declaration of death based on neurological criteria Subject to the standards and procedures established in accordance with this act, an individual whose circulatory and respiratory functions can be maintained solely by artificial means, and who has sustained</li> </ul>
	<ul> <li>act, an individual whose circulatory and respiratory functions can be maintained solely by artificial means, and who has sustained irreversible cessation of all functions of the entire brain, including the brainstem, shall be declared dead. L.1991,c.90,s.3.</li> <li>26:6A-4. Physician to declare death a. A declaration of death upon the basis of neurological criteria pursuant to section 3 of this act shall be made by a licensed physician professionally qualified by specialty or expertise, in accordance with currently accepted medical standards and additional requirements, including appropriate confirmatory tests, as are provided pursuant to this act. b. Subject to the provisions of this act, the Department of Health, jointly with the Board of Medical Examiners, shall adopt, and from time to time revise, regulations setting forth (1) requirements, by specialty or expertise, for physicians authorized to declare death upon the basis of</li> </ul>

neurological criteria; and (2) currently accepted medical standards, including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria. The initial regulations shall be issued within 120 days of the enactment of this act. c. If the individual to be declared dead upon the basis of neurological criteria is or may be an organ donor, the physician who makes the declaration that death has occurred shall not be the organ transplant surgeon, the attending physician of the organ recipient, nor otherwise an individual subject to a potentially significant conflict of interest relating to procedures for organ procurement. d. If death is to be declared upon the basis of neurological criteria, the time of death shall be upon the conclusion of definitive clinical examinations and any confirmation necessary to determine the irreversible cessation of all functions of the entire brain, including the brainstem. L.1991,c.90,s.4.
<b>26:6A-5.</b> Death not declared in violation of individual's religious beliefs The death of an individual shall not be declared upon the basis of neurological criteria pursuant to sections 3 and 4 of this act when the licensed physician authorized to declare death, has reason to believe, on the basis of information in the individual's available medical records, or information provided by a member of the individual's family or any other person knowledgeable about the individual's personal religious beliefs that such a declaration would violate the personal religious beliefs of the individual. In these cases, death shall be declared, and the time of death fixed, solely upon the basis of cardio-respiratory criteria pursuant to section 2 of this act. L.1991,c.90,s.5.
<b>26:6A-6.</b> Immunity granted to health care practitioner, provider, hospital A licensed health care practitioner, hospital, or the health care provider who acts in good faith and in accordance with currently accepted medical standards to execute the provisions of this act and any rules or regulations issued by the Department of Health or the Board of Medical Examiners pursuant to this act, shall not be subject to criminal or civil liability or to discipline for unprofessional conduct with respect to those actions. These immunities shall extend to conduct in conformity with the provisions of this act following enactment of this act but prior to its effective date. L.1991,c.90,s.6.
<b>26:6A-7.</b> Obligations of insurance providers unchanged Changes in pre-existing criteria for the declaration of death effectuated by the legal recognition of modern neurological criteria shall not in any manner affect, impair or modify the terms of, or rights or obligations created under, any existing policy of health insurance, life insurance or annuity, or governmental benefits program. No health care practitioner or other health care provider, and no health service plan, insurer, or governmental authority, shall deny coverage or exclude from the benefits of service any individual solely because of that individual's personal religious beliefs regarding the application of neurological criteria for declaring death. L.1991,c.90,s.7.
<b>26:6A-8.</b> Rules, regulations, policies, practices to gather reports, data a. Pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.) the Department of Health shall establish rules, regulations, policies and practices as may be necessary to collect annual reports from health care institutions, to gather additional data as is reasonably necessary, to oversee and evaluate the implementation of this act. The department shall seek to minimize the burdens of record keeping imposed by these rules, regulations, policies and practices, and shall seek to assure the appropriate confidentiality of patient records. b. The Department of Health, the Board of Medical Examiners, and the New Jersey Commission on Legal and Ethical Problems in the Delivery of Health Care shall jointly evaluate the implementation of this act and report to the Legislature, including recommendations for any changes deemed necessary, within five years from the effective date of this act. L.1991,c.90,s.8.

# Appendix Three Lexicon of Key Terms

# **Medical Tools**<sup>33</sup>

**Standards** are accepted principles for patient management. These are rigidly applied rules, with rare exceptions and known consequences. Standards are used to increase the probability of producing appropriate medical care. They are frequently used to determine if relevant and useful procedures were followed.

**Practice parameters** define effective means of diagnosing, treating and managing various conditions and diseases. Practice standards are typically based on scientific research in the form of randomized, controlled, clinical trials, reports of series, or case studies or expert clinical experience. They are prepared by individuals with expertise in the field. Good practice standards are well-documented and researched statements supported by scientific literature that are valid, reliable, reproducible and clinically relevant, that provide for clinical flexibility, that are subjected to multidisciplinary review and that are regularly updated to reflect current knowledge.

**Clinical practice guidelines** are systematically developed statements to assist in practitioner and patient decisions about appropriate health care for specific clinical circumstances. Practice guidelines may be broad statements or very detailed. They are based on scientific evidence as well as expert opinion. The terms "practice parameters" and "clinical practice guidelines" are often used interchangeably.

**Protocols** describe the process of care for individual patients (through preprinted orders) developed to reflect the most efficacious care and best outcomes for patients with that condition. Protocols can expedite care for routine problems. They are unusually specific to a particular institution.

**Clinical algorithms** are clinical guidelines prepared in a flow chart format, typically describing the process and decisions involved in addressing a specific condition. Alternative diagnostic and treatment approaches are described based on decision points that reflect information or judgments made about the patient.

**Clinical or critical pathways** document essential steps in the diagnosis and treatment of a condition or procedure for individual patients. They document a standard pattern of care to be followed for each patient. Often, specific information on the timing of each intervention is specified, with provision for recording variances and their reasons such that analysis can be performed to modify the pattern of care and thus avoid variances in the future. These pathways are predominantly management tools and are based on clinical information developed in other guidelines or parameters. They are specific to the institution using them.

# Legal Terms

**Act:** A bill that has passed through the various legislative steps required for it and that has become law, as in "an Act of the Commonwealth of Australia". "Act" is synonymous with "statute", "legislation" or "law". <sup>34</sup>

<sup>33</sup> Adapted from "Practice Guidelines Committee develops definitions of term" [online, adapted from *The Physiatrist,* December 1995/January 1996], American Academy of Physical Medicine and Rehabilitation [accessed 26 February 2003], <www.aapmr.org/hpl/pracguide/terms.htm>.

<sup>34</sup> Duhaime, L. *Duhaime's law dictionary* [online], Duhaime & Company [accessed 26 February 2003], <www.duhaime.org/dictionary/diction.htm>.

**Legislation:** Written and approved laws. Also known as statutes or acts. In constitutional law, one would talk of the "power to legislate" or the "legislative arm of government", referring to the power of political bodies (e.g., Parliament) to write the laws of the land.<sup>35</sup>

**Soft law:** Refers to the body of policies, codes and guidelines created by a self-governing body to establish normative codes of conduct for members of a professional community.<sup>36</sup> Soft laws take on legal status—i.e., are embodied in judicial precedent—if used as an authoritative reference in making a decision. However, judges are free to disregard soft law if they believe the standards set by it are inadequate.

**Regulations**: Rules and administrative codes issued by governmental agencies at all levels: municipal, county, state or provincial and federal. Although they are not laws, regulations have the force of law, because they are adopted under authority granted by statutes and often include penalties for violations. <sup>37</sup>

**Standard of care:** The watchfulness, attention, caution and prudence that a reasonable person in the circumstances would exercise. If a person's actions do not meet this standard of care, then his or her acts fail to meet the duty of care, which all people (supposedly) have toward others. Failure to meet the standard is negligence, and any damages resulting therefrom may be claimed in a lawsuit by the injured party. The problem is that the "standard" is often a subjective issue upon which reasonable people can differ.<sup>38</sup>

<sup>35</sup> Dulhaime & Company, op cit.

<sup>36</sup> Adapted from Campbell, A., and Glass, K.C. The legal status of clinical and ethics policies, codes, and guidelines in medical practice and research. *McGill L.J.* 46 (2001) 473.

<sup>37</sup> Law.com dictionary at < <u>http://dictionary.law.com/</u>>,, accessed February 26, 2003.

<sup>38</sup> Law.com dictionary at < <u>http://dictionary.law.com/</u>>, op cit.