Comparison of Provincial and Territorial Legislation Governing Substitute Consent for Research

Gina Bravo,[1,2] Michaël Gagnon,[2] Sheila Wildeman,[3] David T. Marshall,[4] Mariane Pâquet,[2] and Marie-France Dubois[1,2]

RÉSUMÉ

Au Canada, les lois provinciales et territoriales indiquent les circonstances dans lesquelles un subrogé peut être nommé pour représenter un adulte jugé légalement incapable de prendre des décisions pour un ou plusieurs aspects de sa vie. Nous avons cherché des lois provinciales et territoriales qui portaient explicitement sur la prise de décisions par le subrogé à l'égard de la participation à des recherches et avons découvert des différences considérables entre les sphères de compétence canadiennes. Dans certaines provinces/certains territoires, il n'existe aucune directive légale directe à ce sujet. Parmi les différences législatives, entre les sphères de compétence, à l'égard de la subrogation en matière de recherches, on compte : la question de savoir si une intervention judiciaire est nécessaire pour autoriser le subrogé, la question de savoir si la décision relative à la recherche doit être explicitement autorisée de façon préalable pour qu'un mandataire puisse donner son consentement, ainsi que la question de savoir comment s'articulent les seuils de risques et d'avantages au-delà desquels le subrogé ne peut émettre de consentement à l'égard de la recherche. Il est impératif que le gouvernement, les chercheurs et le public canadien révisent les principes qui sous-tendent la prise de décision par des subrogés en matière de recherche, à la lumière de normes nationales et internationales, de manière à rendre cet aspect de la loi et les pratiques de recherche plus clairs et plus cohérents.

ABSTRACT

In Canada, provincial and territorial laws address circumstances in which a substitute decision-maker may be appointed for an adult deemed legally incapable of making decisions in one or more areas of life. We searched for provincial and territorial laws that explicitly address substitute decision-making about research participation, and found significant differences among Canadian jurisdictions. In some provinces and territories there is no direct statutory guidance on the issue. Differences among jurisdictions that address substitute decision-making about research in legislation include whether judicial intervention is required to authorize the substitute decision-maker, whether any advance directive in place must explicitly authorize the decision about research in order for a proxy to consent, and how risk and benefit thresholds beyond which substitute consent to research is prohibited are articulated. It is imperative that government, researchers, and the Canadian public revisit the principles underpinning substitute decision-making about research in light of national and international norms, in order to lend clarity and consistency to this area of law and research practice.

1 Department of Community Health Sciences, Faculty of Medicine, University of Sherbrooke

2 Research Centre on Aging, Sherbrooke University Geriatric Institute

3 Dalhousie Law School

4 Clinical Ethics Committee, Ottawa Heart Institute

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Gina Bravo, Ph.D.
Research Centre on Aging
Sherbrooke University Geriatric Institute

1036 Belvedere South
Sherbrooke, QC J1H 4C4
(gina.bravo@usherbrooke.ca)

Introduction

As the Canadian population ages (Health Canada, 2002), growing numbers of older adults develop diseases characterized by increasing cognitive impairment. According to the Canadian Study of Health and Aging (1994), 8 per cent of Canadians aged 65 and older suffer from dementia. The proportion rises to 35 per cent among those over 85 years of age. In this age group, the prevalence further increases to 65 per cent when all types of cognitive impairment are included (Graham et al., 1997).

In the last two decades or so, researchers have intensified efforts to identify the causes of dementia, find ways to alleviate the suffering it entails, and develop effective prevention and therapeutic strategies (Post & Whitehouse, 1998; Woodward, 1999). In the absence of reliable animal models for investigation, scientific knowledge on cognitive disorders can hardly progress without involving affected individuals (Fisk et al., 1998; Keyserlingk, Glass, Kogan, & Gauthier, 1995; Mohr, Feldman, & Gauthier, 1995; World Medical Association Declaration of Helsinki).

Participation of cognitively impaired adults in research raises complex ethical issues that follow from the fundamental legal requirement for informed consent to participation in research (Alzheimer's Association, 1997; Brodaty et al., 1999; Glass & Lemmens, 2002; Kapp, 2002; Rabins, 1998). At law, all adults are presumed capable of making decisions on matters affecting their interests; however, this presumption is subject to rebuttal.[1] While there can be no direct inference from the presence of a cognitive disorder to the conclusion that a person is legally incapable of making a decision about research participation, in some cases suspicions may be raised among clinicians and researchers. Persons in the early stages of dementia may show little or no impairment of decision-making abilities. However, as the disease progresses, those affected may become increasingly unable to understand the nature of the research or appreciate the consequences of their involvement (American Geriatrics Society Ethics Committee, 1998; American Psychiatric Association, 1998; Feinberg & Whitlatch, 2001; Kim, Caine, Currier, Leibovici, & Ryan, 2001).

Background Legal Protections for Cognitively Impaired Subjects

Many Canadian jurisdictions feature legislation addressing the scope and limits of substitute decision-making authority in health care and other areas. As discussed below, some of these regimes explicitly address substitute decision-making about research. However, substitute decision-making about research (and substitute decision-making generally) is also constrained by more general background laws. For instance, provincial and territorial human rights statutes protect persons from discrimination on the basis of mental disability. This point may be relevant, for example, where a research protocol involving adults with differing degrees of cognitive impairment requires substitute consent as a rule without adequately providing for assessment of individual subjects' decisional capacity. Moreover, criminal charges may be brought against researchers and/or substitute decision-makers who fail to comply with a lawful regime of substitute decision-making and proceed with research in the absence of valid authorization (Glass & Lemmens, 2002).

At common law, the tort of battery arises where persons are subject to medical or other bodily interference in the absence of direct or substitute consent. In addition, negligence actions may be raised against researchers and/or institutions where insufficient disclosure of the risks of participation in research is made to a capable subject or substitute decision-maker. Any common law analysis of the legality of research or substitute decision-making practices must be consistent with the values expressed in the *Canadian Charter of Rights and Freedoms*, for instance its protection of liberty and security of the person (sec. 7) and its advancement of the value of equality, including freedom from discrimination on the basis of mental disability (sec. 15).

Our review of the jurisprudence identified seven decisions in which legal claims arose from experimental procedures or research involving subjects deemed capable of deciding about participation: two were from Alberta,[2] two from British Columbia,[3] two from Quebec,[4] and one from Saskatchewan.[5] Five of these involved capable adults claiming to have undergone an experimental medical procedure without being fully informed of the risks involved. The other two, *Halushka v. University of Saskatchewan* and *Weiss v. Solomon*, also involved capable adults and were founded on incomplete disclosure of the risks involved in scientific studies. No decisions were found that directly address the legality of substitute consent to research; however, the Supreme Court of Canada case *E. (Mrs.) v. Eve*,[6] in which the court

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denied a mother's request for authorization to consent to the non-therapeutic sterilization of her mentally disabled daughter, has been interpreted by some to suggest that the common law precludes substitute consent to any medical intervention that is of no benefit to the individual, including even minimally harmful research interventions (e.g., venipuncture).[7] Continuing uncertainty around the legality of substitute decision-making about research at common law is most problematic in light of the absence of clear or consistent statutory direction on the issue across Canadian jurisdictions.

The conditions precedent to legal authorization of a substitute decision-maker are not directly addressed in the federal laws that regulate research practices. For instance, the good clinical practices set out in the Clinical Trials Regulations under the *Food and Drugs Act*[8] do not explicitly contemplate substitute decision-making about another person's participation in a clinical drug trial. However, Health Canada has adopted international guidelines on the conduct of clinical trials (the ICH Harmonized Tripartite Guideline) to guide interpretation of the *Food and Drugs Act* and Regulations, and this document does deal extensively with the protocol for obtaining substitute consent to participation in clinical trials.[9]

It should also be noted that the governance of research involving persons deemed incapable of deciding about participation in research is significantly shaped by the Tri-Council Policy Statement (TCPS) (Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 1998). Where research is publicly funded, the guidelines under the TCPS must be complied with in order to receive or continue to receive funding. Moreover, these guidelines may function as indicators of the standard of care expected of researchers, whether publicly or privately funded, should an action be raised in negligence (Glass & Lemmens, 2002). Inspired by the *Belmont Report* (1979) and other influential documents on research ethics (Medical Research Council of Canada, 1987; Council for International Organizations of Medical Sciences, 1993; World Medical Association Declaration of Helsinki), the TCPS imposes conditions for involving decisionally incapable adults in research: "Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when: (a) the research question can only be addressed using individuals within the identified group(s); (b) free and informed consent will be sought from their authorized representative(s); and (c) the research does not expose them to more than minimal risks without the potential for direct benefits for them" (article 2.5). Further reference is made to subjects incapable of making decisions, in article 2.7, which requires respect for subjects' dissent, and article 5.3, which states that such subjects "shall not be automatically excluded from research which is potentially beneficial to them as individuals, or to the group that they represent." The policy does not define *authorized representative(s)*.

Beyond these background regimes of human rights law, the common law, and federal criminal law and regulatory policies, it remains that – in Canada – the dominant sources of authority in the area of substitute decision-making are provincial and territorial laws that specifically provide how authorization to make substitute decisions is conferred and what conditions limit that authority. Clinical researchers should be familiar with legislative requirements that apply in their own jurisdiction (Etchells, Sharpe, Walsh, Williams, & Singer, 1996; Lazar, Greiner, Robertson, & Singer, 1996; National Council on Ethics in Human Research, 1996). They should also be aware of the rules in other provinces and territories, especially when designing multi-centre clinical trials. Statistical power considerations often require dementia drug trials to be conducted in several provinces (Mohr et al., 1995). A number of such trials have been carried out in Canada (see, for example, Burns et al., 1999; Feldman et al., 2001; Feldman et al., 2003; Gauthier et al., 1990; Rockwood et al., 1997; Rockwood et al., 2000). Yet variability in existing legislation could affect studies targeting cognitively impaired subjects from different jurisdictions. No recent article could be found in the scientific or legal literature that provides a comprehensive comparison of provincial and territorial laws concerning third-party consent.

Methods

The search for pertinent Canadian legislation and regulations was done mainly on the Internet by one of the authors (MG). The Canadian Legal Information Institute[10] search engine provided the relevant information on the following Canadian provinces: Alberta, Manitoba, New Brunswick, Nova Scotia, Ontario, Quebec, and Saskatchewan. For the other provinces and territories, we went directly to the official government sites via the Canadian Legislation website.[11] All computerized searches used the following key words: *research*, *experimentation*, *experimental*, *proxy*, *substitute*, and *consent*. Given the lack of an effective search engine for the laws of the Northwest Territories, Nunavut, and the Yukon at the time of our research, the statutes of these jurisdictions were examined one by one.

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Table 1: Outline of provincial and territorial legislation specifying who is legally authorized to consent to health care and research on behalf of an incompetent adult

Consent to Health Care	Consent to Research
Alberta: Mental Health Act; Personal Directives Act	
Subsection 28 (1) of the Mental Health Act The patient's agent designated in the personal directive The patient's guardian appointed by the court under the *Dependent Adults Act* The patient's nearest relative (spouse, child, parent, sibling, grandparent, grandchild, uncle or aunt, nephew or niece, any adult person the board designates) The Public Guardian	Section 15 of the Personal Directives Act An agent has no authority to make personal decisions relating to the following matters unless the maker's personal directive contains clear instructions that enable the agent to do so: (c) removal of tissue from the maker's living body . . . for . . . research purposes; (d) participation in research or experimental activities, if the participation offers little or no potential benefit to the maker;
British Columbia: Health Care (Consent) and Care Facility (Admission) Act; Health Care Consent Regulation; Representation Agreement Act	
Sections 11 and 16 of the Health Care (Consent) and Care Facility (Admission) Act The committee of person appointed under the *Patients Property Act* The representative appointed under the *Representation Agreement Act*, if authorized in the representation agreement The temporary substitute decision-maker chosen by the health care provider: the nearest relative (spouse, child, parent, sibling, any other relative) a friend or other person authorized by the Public Guardian and Trustee the Public Guardian and Trustee	Section 1 of the Health Care (Consent and Care Facility (Admission) Act ''health care'' means anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic or other purpose related to health, and includes: c) participation in a medical research program approved by an ethics committee designated by regulation; Subsection 18 (1) of the Health Care (Consent) and Care Facility (Admission) Act and Section 5 of the Health Care Consent Regulation A temporary substitute decision-maker does not have authority to give substitute consent to: (d) removal of tissue from a living human body for . . . medical . . . research; (e) experimental health care involving a foreseeable risk . . . that is not outweighed by the expected therapeutic benefit; (f) participation in a health care or medical research program that has not been approved by an ethics committee; Section 9 of the Representation Agreement Act The same rule applies to the representative unless a consultation certificate was completed by a member of the Law Society of British Columbia.
Manitoba: The Mental Health Act; The Health Care Directives Act; The Vulnerable Persons Living with a Mental Disability Act	
Subsection 28 (1) of The Mental Health Act The proxy appointed in a directive The committee of both property and personal care appointed under *The Mental Health Act* or the substitute decision-maker for personal care appointed under *The Vulnerable Persons Living with a Mental Disability Act* The nearest relative (spouse or partner, child, parent, sibling, grandparent, grandchild, uncle or aunt, nephew or niece) The Public Trustee	Section 14 of The Health Care Directives Act Unless a directive expressly provides otherwise, a proxy cannot consent to (a) medical treatment for the primary purpose of research; (c) the removal of tissue from the maker's body, while living, . . . for the purpose of . . . medical research. Section 93 of The Mental Health Act A committee of both property and personal care may not give consent on the incapable person's behalf to: (a) medical treatment for the primary purpose of research, if the treatment offers little or no potential benefit to the person; (c) the removal of tissue for . . . medical research;

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Table 1: Continued

Consent to Health Care	Consent to Research
	Section 61 of The Vulnerable Persons Living with a Mental Disability Act A substitute decision-maker for personal care has no power to give consent on the vulnerable person's behalf to: (a) medical treatment for the primary purpose of research; (c) the removal of tissue for . . . medical research; (f) participation in an activity or project whose primary purpose is research.
New Brunswick: Mental Health Act; Nursing Home Act	
Subsection 8.6 (2) of the Mental Health Act The patient's guardian appointed by a court of competent jurisdiction The patient's attorney for personal care appointed under the *Infirm Persons Act* The nearest relative (spouse, child, parent, sibling, any other next of kin) A patient advocate	Section 13 of the Nursing Home Act An operator shall . . . c) ensure that no authorized individual or agency is permitted to interview or examine a resident . . . for the purposes of research . . . without . . . the informed consent of the resident or, where the resident is unable to give an informed consent, the informed consent of his next of kin or legal representative;
Newfoundland and Labrador: Advance Health Care Directives Act	
Sections 9 and 10 The patient's substitute decision-maker named in an advance health care directive The patient's guardian appointed by a court or the Director of Neglected Adults appointed under the *Neglected Adults Welfare Act* The patient's nearest relative (spouse, child, parent, sibling, grandchild, grandparent, uncle or aunt, nephew or niece, another relative) The patient's health care professional who is responsible for the proposed health care	Section 5 (3) A consent by a substitute decision-maker to (a) medical treatment for the primary purpose of research; (c) the removal of tissue from the maker's body while living . . . for the purpose of medical research shall have no effect unless the substitute decision-maker is expressly authorized in the advance health care directive to give such consent. Notwithstanding the above paragraph, the common law applies in the conduct of health research where there is no advance health care directive.
Northwest Territories (including Nunavut): Guardianship and Trusteeship Act; Health Care Regulations	
Subsection 11 (2) of the Guardianship and Trusteeship Act The guardian appointed by the Court, if authorized in the guardianship order	Section 1 of the Health Care Regulations The following types of health care are designated as types of health care to which a guardian may not consent, on behalf of a represented person, unless specifically authorized to do so in a guardianship order: (c) experimental treatment; (d) removal of tissue from a represented person . . . for the purposes of . . . medical research;
Nova Scotia: Hospitals Act	
Subsection 54 (2) The patient's guardian appointed by a court under the *Incompetent Persons Act* The guardian named by the patient under the *Medical Consent Act* The patient's spouse or common-law partner The next of kin shown on the patient's hospital records The Public Trustee	

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Table 1: Continued

Consent to Health Care	Consent to Research
Ontario: Health Care Consent Act	
Section 20 The guardian of the person appointed under the *Substitute Decisions Act* The attorney for personal care appointed under the *Substitute Decisions Act* The representative appointed by the Consent and Capacity Board The nearest relative (spouse or partner, child, parent, sibling, any other relative) The Public Guardian and Trustee	Section 6 This Act does not affect the law relating to giving or refusing consent on another person's behalf to . . . 1. a procedure whose primary purpose is research.
Prince Edward Island: Consent to Treatment and Health Care Directives Act	
Section 11 The patient's proxy appointed in a directive The patient's guardian appointed by a court under the *Adult Protection Act* or the *Mental Health Act*, if authorized to give or refuse consent to treatment The patient's nearest relative (spouse, child, parent, sibling) A trusted friend Any other relative A public official	Section 12 Nothing in this Part authorizes a person to make a decision on an incapable patient's behalf with respect to . . . a) subject to any expressed authority given in a directive, a procedure the primary purpose of which is research except where the research is likely to be beneficial to the well-being of the patient;
Quebec: Civil Code of Quebec	
Section 15 The mandatary, tutor or curator The married, civil union or de facto spouse A close relative A person who shows a special interest in the person of full age	Section 21 The mandatary, tutor or curator, provided That the experiment does not involve serious risk to his health; That it has the potential to produce results capable of conferring benefit to the individual or to other persons in the same age category or having the same disease or handicap; That it was approved by an ethics committee; That the prospective subject does not object. The person authorized to consent to any care the person requires in the special case of emergency research.
Saskatchewan: The Health Care Directives and Substitute Health Care Decision-Makers Act	
Subsection 16 (1) The proxy appointed in a directive The personal guardian appointed under the *Adult Guardianship and Co-decision-making Act* The nearest relative (spouse, child, parent, sibling, grand-parent, grandchild, uncle or aunt, nephew or niece)	
Yukon: Health Act[13]	
Subsection 45 (1) The client's attorney appointed under the *Enduring Power of Attorney Act* The guardian appointed by a court of competent jurisdiction The nearest relative (spouse, child, parent, sibling, any other next of kin)	

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The data reported in this article are accurate as of January 1, 2004. They were validated by the deputy minister of justice of every province and territory. Because space is limited, we provide only an abbreviated outline of the pertinent legislation. The official versions of these laws should be consulted for full details. As well, given that legislation may be amended or repealed and new laws may be introduced with time, researchers should consult the extant statutory enactments before undertaking research with human subjects.

Results

Table 1 summarizes the results of our research. It was not our objective to compare legislation governing third-party consent for health care (understood in strictly therapeutic terms). However, during the analysis, it became apparent that the rules governing substitute consent for research were – at least in some jurisdictions – closely linked with those on substitute consent for health care. Therefore, for each province and territory, the left column of the table lists in descending order of priority the persons legally authorized to provide substitute consent to health care, and the right column summarizes the laws that deal explicitly with substitute consent for research. For reasons of space we have not included details of the regimes of substitute decision-making about health care (e.g., in Ontario the decision must accord with the prior wishes of the subject, or where these are indeterminate, with the subject's best interests). The column on health care also excludes legal provisions governing emergencies. The column on research is restricted to studies that require direct interaction between the subject and research team. It does not include provisions relating to the use of administrative data for research.

Discussion

Scientific investigation of cognitive disorders is one of the most ethically challenging areas of contemporary clinical research (Sachs & Cassel, 1990). It pits society's interest in acquiring new knowledge and advancing the general good against the interests (e.g., the interest in bodily integrity) of individuals who lack the capacity to make personal decisions (American Geriatrics Society Ethics Committee, 1998, Keyserlingk et al., 1995).

The doctrine of informed consent for research originated with the Nuremberg Code, which made no provision for third-party authorization of research involving subjects who are incapable of making decisions (Keyserlingk et al.). However, later codes and guidelines have done so (e.g., World Medical Association Declaration of Helsinki; *U.S. Code of Federal Regulations*, 1991; Council of Europe, 1997; Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 1998). These documents typically require the permission of legally authorized representatives before enrolling decisionally incapable subjects in research.

In this study, we were interested in determining how and on whom legal authorization to make substitute decisions about research participation is conferred in the different Canadian provinces and territories, and what limits, if any, are placed on substitute decision-making authority in the research context. In reviewing pertinent legislation, we found some similarities across the country, but also significant differences.

Substitute Decisions about Research: How Is Authority Conferred? What Are the Limits?

In most provinces and territories, a substitute decision-maker may be authorized to make decisions in one or more areas of an adult's life through one of a few alternative legal mechanisms. These include: (1) court-ordered guardianship, (2) operation of a power of attorney or, specifically in the health-care context, an advance directive, and (3) the triggering of conditions contemplated under legislation authorizing substitute decision-making in the absence of court appointment or an advance directive. It is against the background of these alternative legal mechanisms that our table must be interpreted and questions specific to the authority to make substitute decisions about research must be asked. We will discuss each of the three mechanisms in turn, first with reference to the legislation in place in the common law jurisdictions (section A) and then with reference to Quebec's *Civil Code* (section B).

We note in advance that Nova Scotia, Saskatchewan, and the Yukon have no legislation explicitly touching on substitute decisions about research (beyond their *Human Tissue Gift Acts*, which apply after the subject's death). In addition, in Ontario, as discussed below, substitute consent to research is addressed only in its express exclusion from the ambit of that province's health care consent and substitute decision-making legislation. In New Brunswick, the only legislation that explicitly addresses substitute decisions about research is restricted to the nursing home context.

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A. Common Law Provinces

Guardianship Legislation

Guardianship statutes provide for judicial appointment of a guardian authorized to make decisions broadly relating to personal care and/or property, or, where specific limits on the guardian's authority are imposed, a more narrowly focused form of decision. The guardian's authority is contingent upon proof of the adult's incapacity to make the type(s) of decision in question. Here it is important to note that it may not always be clear whether a guardian's decision-making authority encompasses decisions about the subject's participation in research. The wording of the legislation or the judicial order in question may suggest a lack of such authority. This is a complex issue reflected in our legislative table only in our recording the fact that the health care regulations in the Northwest Territories and Nunavut explicitly deny guardians authority to consent to ''medical treatment for the primary purposes of research... unless specifically authorized to do so in a guardianship order.''

Advance Directives Legislation

In a number of provinces and territories, advance directives legislation is available under which persons may appoint a proxy to make health care decisions (under some legislation, decisions relating more broadly to ''personal care''), should they become incapable of making such decisions. This legislation may also allow for attendant directives stipulating how the power of decision should be carried out. An advance directive must be executed by the subject while capable, in accordance with provincial or territorial legislation (where such legislation exists); where such legislation does not exist, advance directives are nonetheless arguably authorized at common law.[12] In Quebec, intervention of the court is required to declare the mandator's incapacity and to legitimate the mandatary's authority (homologation of the mandate under article 2166 of the *Code*); elsewhere in the country, advance directives may be triggered upon determination of the subject's incapacity by a body other than a court (for instance, in the case of health care decisions, a health professional may be authorized to make this assessment).

There is significant variation among advance directives regimes on whether or under what circumstances the substitute or proxy may make decisions about research participation. For instance, Ontario's Substitute Decisions Act, like that province's Health Care Consent Act, explicitly excludes from its purview proxy consent to participation in research, stating that the statute ''does not affect the law'' relating to substitute consent to research. Similarly, the advance directives regimes of Nova Scotia (the Medical Consent Act) and Saskatchewan (the Health Care Directives and Substitute Decision-Makers Act), like the power of attorney regimes in New Brunswick and the Yukon, are silent on the legality of substitute decisions about research. As indicated above, opinions diverge on what constraints may lie upon substitute decision-makers in this regard at common law.

However, the advance directives laws of some provinces do explicitly allow for proxy consent to research under prescribed conditions. This is the case in Alberta, British Columbia, Manitoba, Newfoundland and Labrador, Prince Edward Island, and Quebec. There is significant variation among these regimes on the conditions under which substitute decisions about research may be made. In Manitoba and in Newfoundland and Labrador, the legislation suggests that a proxy appointed under an advance directive may not make a decision about research participation unless that decision was expressly contemplated in the directive. In the other listed jurisdictions, proxies may make substitute decisions about participation in research in the absence of such explicit authorization where specific conditions are met. These conditions vary.

For instance, Alberta precludes proxy consent to ''research or experimental activities'' absent express authorization, if the proposed research or experiment offers ''little or no benefit'' to the subject. Therefore it appears that substitute consent may be given despite lack of explicit authorization where the proposed research indeed offers more than ''little or no benefit''. We would question whether the prospect of personal benefits eliminates the risk of serious harm, and so whether such laws as Alberta's provide sufficient protection for subjects incapable of making decisions. A slightly different formulation is found in PEI's *Consent to Treatment and Health Care Directives Act*, which prohibits substitute or proxy consent to research interventions – subject to express authorization in a directive – unless those interventions are likely to be ''beneficial to the well-being of the patient''. Again, it is a matter for interpretation and argument just how potential risks will be accounted for and weighed against potential benefits in applying this standard.

Another approach is reflected in the advance directives legislation in British Columbia. There, a representative appointed under an advance directive is prohibited from giving substitute consent to certain types of interventions, including ''experimental health care'' involving a foreseeable risk not outweighed by the expected therapeutic benefit, and participation in a ''medical research program'' not approved by

an ethics committee. However, at least the former limitation may be displaced where the maker of the advance directive expressly authorized the intervention and completed a consultation certificate with a member of the Law Society of BC.

Given the low prevalence of advance directives generally and those addressing research in particular (Wendler, Martinez, Fairclough, Sunderland, & Ezekiel, 2002; Bravo, Dubois, & Pâquet, 2003), the situation contemplated by such legislation is unlikely to be encountered as frequently as that in which no advance directive is in place.

Health Care Consent Legislation

The last type of legal mechanism for authorizing a substitute decision-maker is legislation providing for such authorization even in the absence of a court-appointed guardian or an advance directive. For instance, many provinces and territories feature some form of health care consent legislation specifying who may make medical treatment decisions on behalf of a patient deemed by a health professional to be incapable of such decisions. Such legislation tends to rank potential substitute decision-makers in descending order, from the court-appointed guardian or proxy under an advance directive, to a list of close family members, sometimes culminating in contemplation of appointment of a public official. On appointment, the substitute must generally exercise his or her decision-making powers in accordance with specific statutory conditions.

As noted above, the law on substitute decision-making about research is in some jurisdictions intimately bound up with legislation addressing who may make substitute decisions about health care. Here three types of legislation are in play.

1. Health care consent legislation explicitly authorizing substitute consent to research First is legislation addressing substitute decisions about ''health care'' that explicitly includes research within its purview. This is the case with BC's *Health Care (Consent) and Care Facility (Admission) Act*, which defines *health care* to include ''participation in a medical research program approved by an ethics committee designated by regulation.'' Substitute decisions about ''health care'' under this act, which thus include substitute decisions about ethics-review approved research, may be made (in the absence of a court-appointed guardian or advance directive) by a close family member, termed a ''temporary substitute decision-maker''. The temporary substitute's authority to provide consent to research is limited by the requirements that the intervention does not involve removal of tissue, does not constitute ''experimental health care'' involving a foreseeable risk not outweighed by the expected therapeutic benefit, and is not a research program that lacks the approval of a research ethics committee.

Also included under this first category is PEI's *Consent to Treatment and Health Care Directives Act*. The act provides that, in the absence of a court-appointed guardian or proxy under an advance directive, the patient's nearest relative may consent to ''a procedure the primary purpose of which is research'' where that research is likely to be beneficial to the patient's well-being.

2. Health care consent legislation excluding substitute decisions about research from its ambit A second category of legislation addressing substitute decision-making about health care explicitly removes research interventions from the purview of the legislation. This, as noted above, is the case with Ontario's *Health Care Consent Act*. As is the case with substitute decision-makers appointed under an advance directive (or power of attorney for personal care) in that province, then, there is no direct statutory authority for the provision of substitute consent to research by family members authorized as substitute decision-makers about health care. Any authorization of such persons for this purpose must therefore be based on the less certain authority of the common law.

3. Health care consent legislation that is silent on substitute decisions about research The third category of legislation addressing substitute decision-making about health care is that in which research is simply not mentioned. For instance, in Saskatchewan's *Health Care Directives and Substitute Health Care Decision-Makers Act*, a ''health care'' decision is a decision about ''treatment,'' and *treatment* is defined as ''anything that is done for a therapeutic, preventive or palliative purpose related to the physical or mental health of a person''. Some may argue that such a definition does not necessarily exclude research, or at least not all research. For while *research* tends to describe an intervention engaged in for the *primary* purpose of advancing scientific knowledge or the public good, research interventions may nonetheless have incidental therapeutic effects. In response it may be argued that it is incorrect and/or unethical to interpret and apply legislation oriented to substitute decisions about therapeutic medical interventions in a way that blurs the line between therapy and research more than it may already be blurred in the minds of patients and their loved ones. Such an approach may have the effect of obscuring the distinct ethical issues engaged by exposing decisionally incapable persons to risk for the primary purpose of advancing the public good.

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Provincial and territorial legislation generally addressing substitute decision-making about health care should at least specify whether *health care* includes research interventions or not. The better approach would be to institute separate legislation (or discrete provisions in broader substitute consent legislation) reflecting the unique considerations that should inform substitute decision making about research, as distinguished from therapeutic interventions.

B. Quebec's Civil Code

Quebec legislation on substitute decision-making about research differs notably from the laws in the other Canadian provinces and territories. Article 21 of the *Civil Code* comprehensively states the conditions for valid substitute decision-making about research on the part of mandataries appointed under an advance directive or mandate, and curators or tutors standing in the position of a court-appointed guardian. One unique background element of the Quebec regime noted above is the requirement that the mandatary appointed under an advance directive must receive formal court authorization prior to exercising his or her powers of decision. Therefore an added level of legal process is engaged in Quebec's advance directives regime.

Otherwise, there are five main differences distinguishing Article 21 of the *Civil Code* from the statutory provisions of other provinces explicitly addressing substitute decision-making about research. First is the exclusive use of the ill-defined term *experiment* to denote the type of activity under scrutiny, instead of the term *research*. Whether there are substantive implications to be drawn from this is unclear. Second, the *Code* prohibits consent to ''experiments'' involving ''serious risk'' to the subject's health. It is not entirely clear how or if this language of serious risk differs from the more common expression (albeit also difficult to apply with precision) used in the literature on justification of research-related risks, ''more than a minor increase over minimal risk'' (Keyserlingk et al., 1995; Oldham, Haimowitz, & Delano, 1999; Weijer, 2000). However, it is arguable that the Quebec legislation contemplates a higher tolerance for research-related risks than is indicated in the more common formulation. As suggested above, this is not to say that the legislation in the other provinces and territories offers significantly better guidance on the issue of risk assessment and threshold. In the current Canadian research context, assessing risk–benefit ratios of specific studies tends to fall on research ethics boards (REBs). Funding agencies such as the Canadian Institutes of Health Research require research proposals to be approved by an REB before funds are transferred to the investigators. Yet a number of papers have documented the variability among REBs in quantifying research risks and benefits (Clark, 2001; Silverman, Hull, & Sugarman, 2001). Hence, in a province that requires expected benefits to outweigh foreseeable risks, one REB may approve the proposed study while another may not.

A third difference under the *Code* is its explicit legitimation of enrolling decisionally incapable subjects in research that offers no prospect of personal benefits but could benefit others with similar characteristics. This is a position endorsed in the TCPS (cf article 5.3). Some argue (e.g., Marshall [2000, p. 56]) that this part of article 21 of the *Civil Code*, along with its contemplation of participation where risks are less than ''serious,'' may contravene section 7 of the *Charter* by placing the individual's interests in life and security of the person in jeopardy solely in service of the public interest. This contention again engages the fundamental issue of how individual and public interests may justly be balanced in regulating substitute decision-making about research.

Fourth, Quebec is unique in explicitly requiring respect for prospective subjects' dissent (also a requirement under the TCPS). The *Code*, like the TCPS, conditions respect for dissent on the ability of the potential research subject to ''understand the nature and consequences'' of the proposed intervention. Notably, this standard goes some distance to approximating the test for capacity to make the decision in the first place.

Last, Quebec is the only jurisdiction that separately addresses the issue of research in emergencies. In case of sudden decisional incapacity, the law allows close relatives or friends (as contemplated under article 15 of the *Civil Code* on consent to treatment) to consent to research, even if they have not been formally appointed as the subject's substitute decision-maker(s). Recall, however, that such a mechanism is also necessarily in place under the general substitute decision-making regimes of BC and PEI, which authorize family members to make substitute decisions about research where a guardian or proxy under an advance directive is not available.

Conclusion

Researchers in aging will often encounter older adults whose capacity to decide about participation in research is suspect or evidently lacking, yet who have not been formally declared legally incapable of making such decisions. Beyond the specific imperative of determining the adult's legal status as capable or incapable of making the decision, questions arise about the legal mechanisms for authorizing a

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substitute decision-maker in the research context, and/or any specific limitations on such decision-making authority.

We have identified significant areas of inconsistency and uncertainty among Canadian jurisdictions on the issue of who is authorized to make substitute decisions about participation in research, and under what conditions their decisions will be valid. Most notable is the lack of any explicit statutory authority for substitute decision-making about research in many jurisdictions – a particular problem given the lack of clear guidance on this issue at common law. In such jurisdictions – and indeed, where no advance directive is in place that may be deemed to authorize substitute decisions about research, arguably in all jurisdictions except BC and PEI – researchers may be forced to rely on uncertain analogies to legislation oriented to substitute decisions about health care, where such legislation exists, or turn to legal proceedings in which appointment of a guardian authorized to make substitute decisions about research is sought. Such proceedings tend to be expensive and time-consuming, and may lead to emotional turmoil and stigma for proposed wards as well as their families (Kapp, 1999; Menikoff, Sachs, & Siegler, 1992; Miller, Coleman, & Cugliari, 1997).

Given the inconsistencies among Canadian jurisdictions discussed above, whether, for instance, an older adult who is incapable of making decisions could be enrolled in a placebo-controlled drug trial with a risk of substantial toxicity would depend on a number of factors, including where the potential subject resides. Some provinces and territories would prohibit the enrolment in the absence of specific directives (e.g., Manitoba), while others would allow it with additional (variably stated) safeguards (e.g., British Columbia).

Canadians would benefit from a common statutory framework for addressing substitute decision-making about research in each jurisdiction. Obviously such a framework must be sensitive to balancing the individual interest in bodily integrity with the public interest in advancing knowledge about disease. It is therefore imperative that government, researchers, and the Canadian public revisit the principles underpinning substitute consent to research in light of national and international norms, in order to lend clarity and consistency to this important area of law and research practice.

Notes

1 This principle was reaffirmed by the Supreme Court of Canada in *Starson v. Swayze*, [2003] 1 S.C.R. 722.

2 *Cryderman v. Ringrose*, [1977] 3 W.W.R. 109, 6 A.R. 21, 89 D.L.R. (3d) 32 at 33. (Dist. Ct.), affirmed [1978] 3 W.W.R. 481, 89 D.L.R. (3d) 32 (Alta C.A.), and *Zimmer v. Ringrose* (1981), 28 A.R. 69, 16 C.C.L.T. 51, 124 D.L.R. (3d) 215 (C.A.), affirming on other grounds (1978), 13 A.R. 181, 89 D.L.R. (3d) 646 (T.D.), leave to appeal to S.C.C. dismissed (1981), 37 N.R. 289 (S.C.C.).

3 *Coughlin v. Kuntz* (1987), 17 B.C.L.R. (2d) 365, 42 C.C.L.T. 142 (S.C.), affirmed (1989), 42 B.C.L.R. (2d) 108, 2 C.C.L.T. (2d) 42, [1990] 2 W.W.R. 737 (C.A.), and *Grealy v. Kuntz* (July 4, 1996), Doc. Vancouver CA018568 (B.C. C.A.), affirming (March 16, 1994), Doc. Campbell River 670103 (B.C. S.C.), additional reasons at (1994) 27 C.P.C. (3d) 76 (B.C. S.C.).

4 *Morrow v. Hôpital Royal Victoria* (1989), 3 C.C.L.T. (2d) 87, [1990] R.R.A. 41, 35 Q.A.C. 259 (C.A.), leave to appeal to S.C.C. refused (1990), 111 N.R. 239 (note) (*sub nom. Morrow v. Royal Victoria Hospital*) 29 Q.A.C. 80 (note) (S.C.C.), and *Weiss v. Solomon* (1989), 48 C.C.L.T. 280, [1989] R.J.Q. 731, [1989] R.R.A. 374 (Que. S.C.).

5 *Halushka v. University of Saskatchewan* (1965), 52 W.W.R. 608, 53 D.L.R. (2d) 436 (Sask. C.A.).

6 *E. (Mrs.) v. Eve* [1986] 2 S.C.R. 388.

7 See Bernard M. Dickens, "*Eve v. Eve*", Case Comment (1987) 2(1) Can. Fam. L.Q. 103–117 (at 116).

8 *Food and Drug Regulations*, C.R.C., c. 870, s. C.05.010.

9 International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use. (1996, May). *Good clinical practice: Consolidated guideline*. *Yokohama*. Retrieved 20 July 2005 from http://www.ich.org/cache/compo/276-254-1.html

10 Canadian Legal Information Institute website: http://canlii.org

11 Canadian Legislation website: http://www.legis.ca; British Columbia: http://www.qp.gov.bc.ca/statreg; Newfoundland & Labrador: http://www.gov.nf.ca/hoa/sr; Northwest Territories: http://www.iijcan.org/nt/loi; Nunavut: http://www.nunavutcourtofjustice.ca/library; Prince Edward Island: http://www.gov.pe.ca/law/statutes/; Yukon: http://www.justice.gov.yk.ca/legislation

12 *Malette v. Shulman* 72 O.R. (2d) 417 (OCA).

13 These rules will change when Bill 39, entitled Decision-Making, Support and Protection to Adults Act, comes into force.

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