Special Article

Pre-mortem transplantation optimizing interventions: the legal status of consent

[Interventions pre-mortem pour optimiser la greffe d'organes : le statut légal du consentement]

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Purpose: The focus of this paper is on consent issues surrounding pre-mortem transplantation optimizing interventions. First, we explore the potential consequences of the different types of pre-mortem transplantation optimizing interventions that might be used, and we examine the current Canadian practice with respect to these interventions. We then analyze the status of consent to pre-mortem transplantation optimizing interventions under the current legal framework. Finally, we provide recommendations on how to improve the current legal framework.

Principal findings: In Canada, as in many countries in the world today, there is a shortage of organs available for transplantation. Canada's deceased donor rate was 12.8 per million in 2005, a rate that has been stable over the past 12 years. At the end of 2005, the number of Canadians on waiting lists for an organ was 4,025 (125 out of every million Canadians). In total, 283 patients died in 2005 while waiting for new organs. To address the shortage of available organs, a number of changes have recently been made to organ donation practices and protocols. The use of pre-mortem transplantation optimizing interventions is a significant issue in organ donation, and it has become increasingly important to reflect on the use of such interventions, in light of these new practices. "Pre-mortem transplantation optimizing interventions" are interventions that are carried out on a patient, before his or her death, for the purpose of optimizing the chances of successful transplantation.

Conclusions: We argue that consent is legally required and must be express and competent patients have the legal authority to consent; but the law with respect to legal authority to consent on behalf of incompetent patients varies across the

country. We come to the unsettling conclusion that the legality of pre-mortem transplantation optimizing interventions in many circumstances is at best questionable. We provide concrete recommendations (draft statutory text) on how to improve the current legal framework.

CAN J ANESTH 2008 / 55: 7 / pp. 458–469

Objectif : Cet article se concentre sur les questions de consentement entourant les interventions pre-mortem d'optimisation de greffe d'organes. En premier lieu, nous explorons les conséquences potentielles des différents types d'interventions pre-mortem d'optimisation de greffe qui peuvent être utilisées, et nous examinons la pratique canadienne actuelle concernant ces interventions. Ensuite, nous analysons l'état du consentement pour les interventions favorisant une greffe avant le décès selon le cadre légal actuel. Enfin, nous offrons des recommandations quant aux moyens d'améliorer le cadre légal actuel.

Constatations principales : Au Canada, comme c'est le cas dans de nombreux pays à l'heure actuelle, il manque d'organes pour la transplantation. Au Canada, il y avait 12,8 donneurs décédés par million en 2005, et ce taux est stable depuis une douzaine d'années. À la fin 2005, le nombre de Canadiens sur liste d'attente pour un organe était de 4 025 (soit 125 individus pour chaque million de Canadiens). Au total, 283 patients sont décédés en 2005 alors qu'ils étaient en attente d'un nouvel organe. Afin de faire face au manque d'organes disponibles, plusieurs modifications ont

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Funding sources: An earlier version of this paper was made possible through a financial contribution from Health Canada.

Associations: Jocelyn Downie has held contracts with the Canadian Council for Organ and Tissue Donation and Transplantation.

Accepted for publication January 7, 2008.

Revision accepted March 24, 2008.

réemment été apportées aux pratiques et aux protocoles de dons d'organes. Le recours avant le décès à des interventions favorisant une greffe d'organe est une question cruciale dans le processus du don d'organes et, à la lumière de ces nouvelles pratiques, il est devenu essentiel de réfléchir à l'utilisation de telles interventions. Les « interventions avant le décès favorisant la greffe d'organes » sont des interventions pratiquées sur un patient avant sa mort dans le but de maximiser les chances de réussite d'une greffe.

Conclusion : Selon nous, le consentement est requis d'un point de vue légal et doit être explicite, et que les patients compétents disposent de l'autorité légale de consentir ; toutefois, la loi concernant l'autorité légale de consentir au nom de patients non compétents varie d'une province à l'autre. Nous arrivons à la conclusion dérangeante que la légalité des interventions favorisant la greffe d'organes avant le décès est, dans le meilleur des cas, discutable dans de nombreuses situations. Nous proposons des recommandations concrètes (esquisse de texte légal) sur la manière d'améliorer le cadre légal actuel.

In Canada, as in many countries in the world today, there is a shortage of organs available for transplantation. Canada's deceased donor rate was 12.8 per million in 2005, a rate that has been stable over the past 12 years. At the end of 2005, the number of Canadians on waiting lists for an organ was 4,025 (125 out of every million Canadians). In total, 283 patients died in 2005 while waiting for new organs.^A To address the shortage of available organs, a number of changes have recently been made to organ donation practices and protocols. Some jurisdictions have implemented policies that require hospitals to report all deaths and imminent deaths to their local transplant agency.^B In some jurisdictions, health care providers are now obligated to request the consent of the deceased person's family for organ donation (required request) or to inform the family of the option to donate (routine inquiry).^C In a further effort to in-

crease the pool of eligible donors, the transplant agency in Ontario, the Trillium Gift of Life Network, has begun to accept organs from individuals who are declared dead, according to cardiocirculatory determination of death (CDD),^D in addition to those individuals declared dead, according to neurological determination of death (NDD).^E

The use of pre-mortem transplantation optimizing interventions is a significant issue in organ donation, and it has become increasingly important to reflect on the use of such interventions, in light of the new practices mentioned above. "Pre-mortem transplantation optimizing interventions" are interventions that are carried out on a patient, before his or her death, for the purpose of optimizing the chances of successful transplantation.^F Ventilation for the purpose of organ donation (VPOD), also referred to as elective ventilation or non-therapeutic ventilation, is the most common transplantation optimizing intervention. In NDD protocols, VPOD might be used on a patient with severe brain injury, in order to sustain the organs, while waiting to see whether brain death will develop and organ donation will be possible.^G Under policies that mandate the reporting of imminent deaths, VPOD

D We have chosen to use the term "cardiocirculatory determination of death" (CDD), rather than "donation after cardiocirculatory death" (DCD), to refer to organ donation from individuals who are declared dead, according to cardiocirculatory determination of death methods, to avoid the perception that there are two kinds of death: cardiac death and brain death. We want to reinforce the understanding of CDD and NDD as alternative methods of determining death, rather than two types of death.

E Trillium Gift of Life Network. Ontario's Organ and Tissue Donation Agency. Backgrounder – Donation after cardiac death (DCD) (June 28, 2006). Available from URL; <http://www.giftoflife.on.ca/page.cfm?id=3DA4FCC9-DE5A-4642-A294-6827375C733C>.

F We have identified these interventions as "transplantation optimizing" because, in our opinion, this is the most accurate and the most specific description of the kinds of interventions under consideration. We do not use the label "non-therapeutic", because some of the interventions could be said to be therapeutic; i.e., they could sustain life for some time. They well may not be in the best interests of the patient, but "non-therapeutic" is not synonymous with "not in the best interests of." The therapeutic/non-therapeutic distinction, therefore, does not capture all, and only, the interventions at issue. "Transplantation optimizing" does so. We reject the label "elective", as there are many reasons, other than transplantation optimization, for which someone might consent to an intervention.

G Canadian Council for Donation and Transplantation. Severe Brain Injury to Neurological Determination of Death: A Canadian Forum (Report and Recommendations) (Vancouver, British Columbia, April 9-11, 2003).

A Canadian Institute for Health Information, Canadian Organ Replacement Register. e-Statistics on Organ Transplants, Waiting Lists and Donors. Available from URL; http://secure.cihi.ca/cihiweb/disPage.jsp?cw_page=reports_corstats_e.

B British Columbia, Manitoba and Ontario have mandatory reporting policies. *Human Tissue Gift Act*, R.S.B.C. 1996, c. 211, s.15, s.12(1); *The Human Tissue Gift Act*, S.M. 1987-88, c. 39, ss.4 -4.2; *Trillium Gift of Life Network Act*, R.S.O. 1990, c. H.20, ss.8.1 - 8.6.

C Manitoba, New Brunswick and Nova Scotia have required request policies. *The Human Tissue Gift Act*, S.M. 1987-88, c. 39, ss.4 -4.2; *Human Tissue Gift Act*, S.N.B. 2004, c. H-12.5, s. 8(1)-(4); *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215, s. 6A.

might be used to sustain the patient, while waiting for an assessment from the transplant agency.¹ Under required request or routine inquiry models, VPOD might be used to sustain the patient, until the family can be located and their consent can be sought. In the context of CDD, VPOD might be used to preserve the patient's organs, prior to the withdrawal of life support and the determination of death. In addition, under CDD protocols, other pre-mortem transplantation optimizing interventions might be used. These include: trial interruptions of mechanical ventilation; the administration of analgesic agents; anticoagulants; vasodilators; and the insertion of catheters.^{2,H}

It is important to emphasize that the focus of this paper is on consent issues surrounding pre-mortem transplantation optimizing interventions. There are, therefore, two very important limits on the scope, which must be mentioned here. Interventions aimed at other objectives not in the best interests of the patient, occur in other contexts in everyday clinical practice. For example, ventilation might be prolonged as part of a negotiated process between the dying patient's family members and clinicians, as they seek to synchronize expectations and decisions in the intensive care unit.³ Ventilation might be extended in order to give family members more time with the dying patient or to allow for a family member's arrival. Interventions with controversial objectives are also sought; for example, male circumcision and surgical removal of healthy limbs. However, consent issues involving the use of both sorts of interventions, are outside the scope of this paper. In addition, there are important legal and ethical issues, other than consent, that surround pre-mortem transplantation optimizing interventions. For example, the definition and determination of death and CDD protocols are complex and unsettled issues for law and ethics. Again, these issues lie outside the scope of this review and must remain the topic for other papers.

Some work has been done on ascertaining the opinions about pre-mortem transplantation optimizing interventions.¹ There has also been much analysis of

the practice of transplantation optimizing interventions, from an ethical perspective.⁴⁻⁶ However, there has been no comprehensive legal analysis of the consent issues associated with the practice. This paper will provide such an analysis.

First, we explore the potential consequences of the different types of pre-mortem transplantation optimizing interventions that might be used, and we examine the current Canadian practice with respect to these interventions. We then analyze the status of consent to pre-mortem transplantation optimizing interventions under the current legal framework. Finally, we provide recommendations on how to improve the current legal framework.

The potential consequences of pre-mortem transplantation optimizing interventions^J

Pre-mortem transplantation optimizing interventions can be grouped into three categories, according to their potential consequences: those that might prolong life, where a longer life is not wanted; those that might result in a persistent, vegetative state; and those that might hasten death.

First, VPOD might be used in anticipation of NDD, in order to sustain the organs while waiting to see whether brain death will occur, following which the patient would be an eligible organ donor. In CDD protocols, VPOD might be used to preserve the patient's organs until they can be removed for donation.^K In both cases, VPOD will extend the process

In the second scenario, consent to organ donation had been obtained, but specific consent to the interventions had not yet been obtained. Only half of the health care professionals believed that it was not acceptable to perform the interventions in this case (52% for medical procedures, 47% for medications). In the third scenario, consent to organ donation and specific consent to the interventions had both been obtained. Only ten percent of health care professionals believed that it was not acceptable to perform the interventions in this case. *Canadian Council for Donation and Transplantation (CCDT)*. Health Professional Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation after Cardiac Death (August 2006) at 35-38. Available from URL; <http://www.ccdt.ca/english/publications/surveys.html>.

H *The Canadian Council for Donation and Transplantation*. Donation After Cardiac Death: A Canadian Forum (Report and Recommendations) (Vancouver, British Columbia, February 17-20, 2005).

I In a 2006 survey, health care professionals were asked questions about the acceptability of such interventions in cardiac death determination of death. Three different consent scenarios were presented. In the first scenario, consent to organ donation had not yet been obtained. The majority of health care professionals believed that it was not acceptable to perform the interventions in this case (81% for medical procedures, 80% for medications).

J There are a number of post-mortem interventions that might be used: blood testing for donor eligibility; vessel cannulation; in-situ perfusion; administration of anticoagulants and vasodilators; re-institution of chest compressions; mechanical ventilation; extracorporeal circulation and oxygenation. *CCDT*. Donation After Cardiac Death: A Canadian Forum (Report and Recommendations) (Vancouver, British Columbia, February 17-20, 2005) at 73.

K Outside of the Canadian Critical Care Society's (CCCS) Statement, VPOD has not been formally addressed in Canada. There is no sanctioned conduct in this area, and there is vari-

of dying and, thus, prolong life, where a longer life might not always be wanted by, or consistent with, the prior wishes of the patient.⁷ Secondly, with VPOD, there is a small chance that the patient will progress to a persistent vegetative state, instead of death.⁸ Thirdly, in CDD protocols, there are a number of pre-mortem transplantation optimizing interventions that might hasten death. A patient might undergo trial interruptions of mechanical ventilation, in an effort to determine how quickly he or she will likely progress to asystole.^{1,9} Patients must progress swiftly or organ function will be compromised. This procedure carries a risk of destabilizing the patient's cardiopulmonary system. Analgesic agents (e.g., morphine) might be administered to minimize any discomfort the patient might be feeling during the trial withdrawals. This can depress the patient's respiratory drive.² Anticoagulants (e.g., heparin) might be administered to prevent thrombotic obstruction of blood vessels that can occur after the arrest of circulation. This treatment might aggravate bleeding.^H Vasodilators (e.g., phen-tolamine) might be used to enhance organ blood flow, which can cause a transient decrease in blood pressure. Catheters might be inserted, pre-mortem, for post-mortem perfusion of organs with preservatives. This might require escalation of analgesics, sedatives, or anesthetic agents, which can destabilize the patient's cardiovascular system.²

The practice of pre-mortem transplantation optimizing interventions in Canada

In Canada, pre-mortem transplantation optimizing interventions are used in three contexts: within NDD protocols; within CDD protocols; and within mandatory reporting of imminent death regimes.

First, in all provinces, except Ontario, eligibility for organ donation is restricted to individuals that have been declared dead, according to neurological criteria. In NDD protocols, VPOD might, therefore, be used on a patient with severe brain injury, in order to see whether brain death will develop and whether organ donation will be possible.^G

Secondly, before the advent of brain death criteria

in the 1960's, CDD was the Canadian norm.^M For the last two decades, however, individuals who have been declared dead, by reference to loss of cardiac function, as opposed to neurological function, have been considered potential tissue donors only; they have not been eligible to donate organs for transplantation.^E But recently, the situation changed again; in June 2006, the first CDD organ transplant was performed since the introduction of brain death criteria. Doctors at The Ottawa Hospital successfully performed kidney transplants using a donor who died of heart failure.^N The Ottawa Hospital, the London Health Sciences Centre in London, Ontario, and St. Michael's Hospital in Toronto are currently implementing CDD programs.^O Other provinces are assessing the legally and ethically controversial possibility of introducing CDD.^E Under CDD protocols, VPOD might, therefore, be used to preserve the patient's organs for transplantation. The other transplantation optimizing interventions, described in the previous section, might also be used to optimize the transplant outcome.

Thirdly, in British Columbia, Ontario, and Manitoba, hospitals must notify their local transplant agency of all imminent deaths^P [*B.C. Reg.* 65/99, s. 3(1); *Trillium Gift of Life Network Act*, R.S.O. 1990, c. H.20, s. 8.1(1); *The Human Tissue Gift Act*, S.M. 1987-88, c. 39, s. 4(1)]. Mechanical ventilation might be used to sustain patients, while waiting for an assessment from the transplant agency.¹ Ventilation, in such circumstances, is VPOD; a decision has been made that the death of the patient is inevitable, and the ventilation is begun, or continued, in order to secure the viability of the organs for transplantation.

Legal status of consent to pre-mortem transplantation optimizing interventions

Three major questions must be answered in order to understand the legal status of consent to pre-mortem transplantation optimizing interventions.

able practice. CCCS. CCCS Position Paper on Organ and Tissue Donation (Executive Summary) (Lake Louise, Alberta, Jan 22-25, 2001) at 11-12. Available from URL; <http://www.canadiancriticalcare.org/index2.html>

L. Asystole is defined as "complete cessation of cardiac function; that is, absence of systole and electrical activity." *CCDT. Donation After Cardiocirculatory Death. : A Canadian Forum (Report and Recommendations)* (Vancouver, British Columbia, February 17-20, 2005) at 49.

M The Canadian Council for Donation and Transplantation.

Increasing organ donation in Canada: donation after cardiocirculatory death: background to media release. (May 3, 2005). Available from URL; <http://www.ccdt.ca/english/media/media-pdfs/May2005-Media-Backgrounder.pdf>.

N *The Ottawa Hospital and Ontario Trillium Gift of Life Network Media Release*. New era for organ donation in Canada: donation after cardiac death performed successfully in Ottawa (June 27, 2006). Available from URL; <http://www.giftoflife.on.ca/page.cfm?id=F97F1751-94B5-4373-94B0-7AA953B2B704>.

O *Atack E*. Unique organ transplant boosts hope (June 27, 2006) *Canoe - cnews*. Available from URL; <http://cnews.canoe.ca/CNEWS/Canada/2006/06/27/1656322-cp.html>.

P *B.C. Reg.* 65/99, s. 3(1).

FIGURE 1 Types of legally valid consent.

First, is consent required? Secondly, if so, must that consent be express; i.e., explicitly reference pre-mortem transplantation optimizing interventions? Thirdly, if consent is required, who has legal authority to provide such consent? In this section, we will argue that consent is legally required, and it must be express. We will also argue that competent patients clearly have the legal authority to consent to pre-mortem transplantation optimizing interventions; but the law varies across the country and is frequently uncertain with regard to who has the legal authority to consent on behalf of incompetent patients. This means that the legality of pre-mortem transplantation optimizing interventions in many, if not most, circumstances is, at best, questionable.

A. Consent is required

In Canadian law, it is well established that consent is required for all medical interventions, with two exceptions [*Reibl v. Hughes*, [1980] S.C.J. No. 105, 2 S.C.R. 880; *Ciarlariello v. Schacter*, [1993] 2 S.C.R. 119].¹⁰ The first exception is referred to as the emergency exception; i.e., if a patient is incapable of consenting and a substitute decision-maker or valid instruction directive are not available, a doctor may proceed without consent, “where the procedure or treatment is immediately necessary in order to save [the] life or preserve [the] health”, of that individual.¹¹ The second exception exists where there is legislation that authorizes treatment without the patient’s consent. This is seen in public health legislation and

mental health legislation and is confined to situations where there is an overriding, public interest and concern of preventing harm to others or, sometimes, to self.¹¹

Pre-mortem transplantation optimizing interventions do not fall under either of these exceptions. First, the emergency exception is not met, because situations potentially involving transplantation optimizing interventions do not generally arise without there being time to seek consent from the patient or from the patient’s substitute decision-maker. Furthermore, even if there is no time, initially, to seek consent (for example, a motorcycle accident victim is brought to the emergency department, and no family can be reached), there will, subsequently, be time. Once a substitute decision-maker is available, the health care providers cannot proceed without consent. Thus, these interventions clearly do not fit within the limits of the emergency exception. Secondly, there is no legislation that authorizes transplantation optimizing interventions without the patient’s consent; so the statutory exception does not apply.

Therefore, consent is required for pre-mortem transplantation optimizing interventions. The types of legally valid consent are presented in Figure 1.

B. Consent must be express

There are two forms of consent in Canadian law: express and implied. Express consent occurs when the patient has explicitly authorized the medical procedure.¹² Implied consent can be broken up into two

FIGURE 2 Whether valid consent for pre-mortem transplantation optimizing interventions is possible under current law.

types, subsumed and inferred-from-conduct. Inferred-from-conduct consent occurs when “a person, in the shoes of the health care provider, would reasonably infer, from the circumstances, that the patient consented.”¹³ There are two forms of subsumed consent: “[t]he first arises where the intervention at issue is, in effect, a sub-procedure of, or is necessarily incidental to, the procedure explicitly consented to”¹³, and “[t]he second...arises where the explicit consent to a particular procedure contains a blanket consent to other, unspecified procedures.”¹³

Consent to pre-mortem transplantation optimizing interventions cannot be considered implied by consent to organ donation. Inferred-from-conduct consent cannot be argued, because there is no physical act that a potential donor carries out that would

reasonably suggest consent to these interventions. It is unjustifiable to infer that consent to organ and tissue donation reasonably suggests consent to transplantation optimizing interventions, given the widespread lack of knowledge about the existence, nature, and consequences of the process.

Nor can subsumed consent be argued. Sub-procedure consent cannot be argued, because pre-mortem transplantation optimizing interventions are not “necessarily incidental to” organ donation. The interventions are related to organ donation, in that the purpose of performing the procedures is to optimize the transplant outcome and to actualize the intent to donate; however, organ donation can undoubtedly be done without the use of pre-mortem interventions.

Blanket consent is not applicable, because there is

no blanket consent clause in organ donation consent forms. Consent is limited to the use of the donor's body, or specified body parts, after death.^Q Further, there is a chance that the interventions will hasten death or will leave the patient in a persistent, vegetative state, risks that many people would consider to be significant. The law requires specific consent for procedures that carry a significant risk.¹⁴

Therefore, express consent is necessary for pre-mortem transplantation optimizing interventions.

C. Competent patients have the authority to provide express consent to pre-mortem transplantation optimizing interventions

If the patient is competent, it is clear that their express, free, and informed consent to pre-mortem transplantation optimizing interventions, for the purpose of organ donation, is legally necessary and sufficient.

D. Who has the authority to consent on behalf of incompetent patients?

OVERVIEW

Pre-mortem transplantation optimizing interventions are, and would most commonly be, done after a patient has become incompetent. Therefore, the question as to who has the authority to consent, on a patient's behalf, is absolutely critical. Unfortunately, it is a question that is difficult to answer in a concise and definitive manner. In searching for answers, one must consider multiple sources of law, for example: human organ and tissue donation legislation; consent legislation; advance directives legislation; the Quebec *Civil Code*; and the common law. One must take these sources of law into account, in multiple jurisdictions, as they operate at a provincial/territorial level (with the common law operating at both the provincial/territorial level and the national level). The flow chart (Figure 2) summarizes our conclusions. Consider, now, the details of the arguments, with respect to the various relevant sources of law in Canada, which lead to these conclusions.

1. Human organ and tissue donation legislation

Under provincial organ and tissue donation legislation, there is no provision under which an individual can consent, in advance of incompetence, to pre-mortem transplantation optimizing interventions for the purpose of organ donation. Consent to post-

mortem donation is not a valid consent to pre-mortem transplantation optimizing interventions, because post-mortem donation consent is limited to the use of a person's body, or body parts, for specified post-mortem purposes, and the consent only becomes effective on the death of the donor. [*Personal Directives Act*, R.S.A. 2000, c. P-6; *Consent to Treatment and Health Care Directives Act*, R.S.P.E.I. 1988, c. C-17.2; *Personal Directives Act*, S.N.W.T. 2005, c. 16]

Under provincial organ and tissue donation legislation, an individual's next-of-kin has no authority to consent to pre-mortem transplantation optimizing interventions. Again, for post-mortem donation, consent is limited to the use of a person's body, or body parts, for specified purposes, and the consent only becomes effective on the death of the donor [*Human Tissue Gift Act*, R.S.N.S. 1989, c. 215, s. 5].

2. Instruction directive legislation

In British Columbia, New Brunswick, Nova Scotia, Nunavut, Ontario, Quebec, and the Yukon, there is no legislation that authorizes the making of an instruction directive (a document made by an individual, while competent, that sets out what decisions are to be made once the maker becomes incompetent). In the remaining provinces and territories, there are three jurisdictions, Alberta, Prince Edward Island, and the Northwest Territories, where it is clear that consent to pre-mortem transplantation optimizing interventions would likely be valid under instruction directive legislation [*Personal Directives Act*, R.S.A. 2000, c. P-6; *Consent to Treatment and Health Care Directives Act*, R.S.P.E.I. 1988, c. C-17.2; *Personal Directives Act*, S.N.W.T. 2005, c. 16]. For example, in Prince Edward Island, an instruction directive may "stipulate treatment, procedures, or medication that the maker authorizes, or refuses to consent to, or directs to be discontinued, in the circumstances set out in the directive" [*Consent to Treatment and Health Care Directives Act*, R.S.P.E.I. 1988, c. C-17.2, s.20(2)]. In Saskatchewan and Manitoba, we would argue that an individual could not consent to the interventions under instruction directive legislation, because the interventions are excluded from the definition of "treatment." [*Health Care Directives and Substitute Decision Makers Act*, S.S. 1997, c. H-0.001 s.2(1)(h); *The Health Care Directives Act*, S.M. 1992, c. 33, s. 1]. For example, Manitoba's *Health Care Directives Act* defines "treatment" as "anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic, or other health-related purpose" [*The Health Care Directives Act*, S.M. 1992, c. 33, s. 1]. While pre-mortem transplantation optimizing

Q Ontario's organ donation card. Available from URL; <http://www.giftoflife.on.ca/page.cfm?id=3F79E442-F7FD-4057-AA63-7B0279A17EF1>.

interventions are done for a purpose related to the health of the potential recipient, they are not done for any of the purposes listed in the legislation, in relation to the patient/potential donor. In Newfoundland, we would argue, similarly, that an individual could not consent to pre-mortem transplantation optimizing interventions in an instruction directive, because the consent would be valid only if the interventions were found to be “health care treatment” and, again, these interventions are not health care treatment for the individual [*Advanced Health Care Directives Act*, S.N.L. 1995, c. A-4.1]. Therefore, we would argue that it is unlikely that an individual could consent to pre-mortem transplantation optimizing interventions, through an instruction directive, in any jurisdiction outside of Alberta, Prince Edward Island, and the Northwest Territories.

3. Instruction directives at common law

At common law (judge made law based on past cases and a core set of values), both of the two leading cases on an individual’s right to have his or her prior competent wishes respected, come from the Ontario Court of Appeal, through the 1990 case *Malette v. Shulman* [*Malette v. Shulman* (1990), 72 O.R. (2d) 417, 67 D.L.R. (4th) 321 (C.A.)] and the 1991 case *Fleming v. Reid* [*Fleming v. Reid* (1991), 4 O.R. (3d) 74, 82 D.L.R. (4th) 298 (C.A.)]. In *Malette v. Shulman*, the patient was brought, unconscious, to an emergency room, after she had been in a motor vehicle accident. The patient was a Jehovah’s Witness who carried a card that clearly expressed her refusal of any form of blood products under any circumstances. The doctor administered blood transfusions, despite having read the written objection. The Court found the card to be a valid instruction directive and, thus, held the doctor liable for battery. The decision was grounded in recognition of the fundamental principle of respect for individual autonomy, which underlies the doctrine of informed consent [*Malette v. Shulman* (1990), 72 O.R. (2d) 417, 67 D.L.R. (4th) 321 (C.A.)].

In *Fleming v. Reid*, the patients were involuntary, incompetent psychiatric patients who had previously, while competent, expressed refusals to be treated with neuroleptic drugs. Their doctor wished to treat them with these drugs and believed this decision to be in their best interests. The Court ordered that the patient’s competent wishes be respected:

A patient, in anticipation of circumstances wherein he or she may be unconscious or otherwise incapacitated and thus unable to contemporaneously express his or her wishes about a particular form of medical treatment, may

specify in advance his or her refusal to consent to the proposed treatment. A doctor is not free to disregard such advance instructions, even in an emergency [*Fleming v. Reid* (1991), 4 O.R. (3d) 74, 82 D.L.R. (4th) 298 (C.A.)].

Although these cases would be persuasive legal precedent in other jurisdictions, the decisions are only binding in Ontario. Furthermore, both cases involved refusals of treatment rather than consent to treatment and, thus, neither case would be directly on point, in regard to the legal effect of an instruction directive providing consent to pre-mortem transplantation optimizing interventions. Also, neither case provides details regarding the requirements of a valid instruction directive at common law; for example, it is unclear whether the directive would have to clearly indicate that the consent was informed. There is, therefore, little by way of relevant guidance available in the common law.

4. Proxy directive legislation

Alberta and the Northwest Territories are the only jurisdictions in which a proxy could clearly provide legally valid consent to pre-mortem transplantation optimizing interventions under advance directive legislation (legislation establishing the legal status of instruction and/or proxy directives) [*Personal Directives Act*, R.S.A. 2000, c. P-6. *Personal Directives Act*, S.N.W.T. 2005, c.16].^R In New Brunswick and Nunavut, there is no legislation that authorizes the making of proxy directives (a document made by an individual, while competent, that sets out who is to make decisions on behalf of the directive maker once the maker becomes incompetent). In the Yukon, Saskatchewan, Prince Edward Island, and Manitoba, a proxy, arguably, could not consent to the interventions under advance directive legislation, because the interventions are excluded from the statutory definitions of “treatment” or “health care”. [*Decision-Making Support and Protection to Adults Act*, S.Y. 2003, c. 21; *Health Care Directives and Substitute Decision Makers Act*, S.S. 1997, c. H-0.001; *Consent to Treatment and Health*

R For example, under the Alberta legislation: “s.14(1) Unless a personal directive provides otherwise, an agent has authority to make personal decisions on all personal matters of the maker.” and “s.15 Despite section 14, 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 (i) for implantation in the body of another living person pursuant to Part 1 of the Human Tissue Gift Act.” Clearly, with clear instructions, the agent has the relevant authority.

Care Directives Act, R.S.P.E.I. 1988, c. C-17.2; *The Health Care Directives Act*, S.M. 1992, c. 33]. In the remaining provinces and territories, it is doubtful whether pre-mortem transplantation optimizing interventions would fall within the scope of proxy directive legislation. [*Health Care (Consent) and Care Facility (Admission) Act*, R.S.B.C. 1996 (Supp.), c. 181, s. 19(3); 45 *Substitute Decisions Act*, S.O. 1992, c. 30, s. 66(4); *Consent to Treatment and Health Care Directives Act*, S.P.E.I. 1996, c. 10, s. 13(2); *Care Consent Act*, S.Y. 2003, c. 21, Sched. B, s. 20(6)]

If pre-mortem transplantation optimizing interventions were determined to fall within the scope of proxy directive legislation, as in Alberta and the Northwest Territories, the ability of a proxy to consent to these interventions would depend on the content of the directive, the knowledge of the proxy, or whether these interventions could be viewed as being in the best interests of the potential donor. In general, the legislation contemplates three different scenarios. If there are clear instructions contained in the directive, or if the incompetent adult's prior competent wishes are known, then they will be determinative. If the adult's instructions or wishes are not known, the proxy must base the decision on his or her knowledge of the adult's beliefs and values. If the proxy does not know the adult's beliefs or values, then he or she must make the decision based on what is in the adult's best interests. British Columbia, Ontario, Prince Edward Island, and the Yukon are the only jurisdictions that provide guidelines for the determination of best interests.¹¹ In general, four factors are to be considered: whether the incapable adult's condition or well-being is likely to be improved, or will not deteriorate, because of the proposed treatment; whether the incapable adult's condition or well-being is likely to improve without the proposed treatment, or is not likely to deteriorate without it; whether the benefit, the incapable adult is expected to obtain from the proposed treatment, outweighs the risk of harm to him or her; and whether a less restrictive, or less intrusive, treatment would be as beneficial as the proposed treatment.

A proxy could, therefore, consent to pre-mortem transplantation optimizing interventions in some jurisdictions if the incompetent adult had expressed a prior competent wish to undergo the interventions, or if, on the basis of the incompetent adult's beliefs and values, the proxy believes that he or she would consent to the interventions. The mere fact that the adult wanted to be an organ donor is not sufficient evidence to support a substitute judgment argument, for the same reasons as, as explained above, consent to organ donation does not establish a claim of implied consent to pre-

mortem transplantation optimizing interventions for the purpose of organ donation. Apart from these two options, it is doubtful that a proxy could consent to the interventions under proxy directive legislation. It is unlikely that consent could be based on a best interests analysis, even if the adult wanted to be an organ donor, because the incompetent adult's condition will not improve, as a result of the interventions, and there is a risk of harm.

5. Proxies at common law

At common law, the only substitute decision-makers who have legal authority to consent on behalf of an incompetent adult, are a court-appointed guardian or a court acting under its *parens patriae* jurisdiction.¹⁴ Canadian courts have yet to consider the legal status of substitute consent from someone who does not fall into one of these two categories. Thus, apart from a court-appointed guardian or a court acting under its *parens patriae* jurisdiction, the common law does not permit anyone to consent to treatment on behalf of an adult patient who lacks capacity.

At common law, a court-appointed guardian must only consent to treatment that would be in the patient's best interests [*Re Eve*, [1986] 2 S.C.R. 388, 31 D.L.R. (4th) 1]. The same restriction applies to a court acting under its *parens patriae* jurisdiction. In the 1986 case *Re Eve*, the Supreme Court of Canada reviewed the basis for the *parens patriae* jurisdiction:

The *parens patriae* jurisdiction is...founded on necessity, namely the need to act for the protection of those who cannot care for themselves. The Courts have frequently stated that it is to be exercised in the "best interest" of the protected person, or again, for his or her "benefit" or "welfare." [*Re Eve*, [1986] 2 S.C.R. 388, 31 D.L.R. (4th)]

If the incompetent adult's prior competent wishes with respect to pre-mortem transplantation optimizing interventions were known, giving effect to those wishes would arguably be determined to be in the adult's best interests. However, if the adult's prior competent wishes with respect to the interventions were unknown, the interventions would likely be found not to be in the adult's best interests. This would be true, even if the adult wanted to be an organ donor because, as explained above, consent to organ donation does not establish a claim of implied consent to pre-mortem transplantation optimizing interventions.

6. Consent legislation

In Alberta, Manitoba, New Brunswick, the Northwest

Territories, and Nunavut, there is no comprehensive consent legislation. Therefore, a substitute decision-maker could consent to pre-mortem transplantation optimizing interventions, only through a guardianship order (Alberta, the Northwest Territories, Nunavut) [*Dependant Adults Act*, R.S.A. 2000, c. D-11; *Guardianship and Trusteeship Act*, S.N.W.T 1994, c. 29; *Guardianship and Trusteeship Act*, S.N.W.T 1994, c. 29 as duplicated for Nunavut by s. 29 f the *Nunavut Act*], the appointment of a Public Trustee (Manitoba) [*Public Trustee Act*, C.C.S.M. c. P275], or a power of attorney under seal (New Brunswick) [*Infirm Persons Act*, R.S.N.B. 1973, c. I-8]. However, in order for the consent to be legally valid, the interventions would have to be found to be “medical treatment” (Alberta, Manitoba, the Northwest Territories, Nunavut) [[*Dependant Adults Act*, R.S.A. 2000, c. D-11; *Guardianship and Trusteeship Act*, S.N.W.T 1994, c. 29; *Guardianship and Trusteeship Act*, S.N.W.T 1994, c. 29 as duplicated for Nunavut by s. 29 f the *Nunavut Act*; *Public Trustee Act*, C.C.S.M. c. P275] or “personal care” (New Brunswick) [*Infirm Persons Act*, R.S.N.B. 1973, c. I-8]. In some of the provinces with comprehensive consent legislation (British Columbia, Ontario, Prince Edward Island, the Yukon, and Saskatchewan), a substitute decision-maker, arguably, could not consent to pre-mortem transplantation optimizing interventions under the legislation, because the interventions are excluded from the definitions of “treatment” or “health care” [*Health Care (Consent) and Care Facility (Admission) Act*, R.S.B.C. 1996 (Supp.), c. 181, s. 19(3); 45 *Substitute Decisions Act*, S.O. 1992, c. 30, s. 66(4); *Consent to Treatment and Health Care Directives Act*, S.P.E.I. 1996, c. 10, s. 13(2); *Care Consent Act*, S.Y. 2003, c. 21, Sched. B, s. 20(6); *Health Care Directives and Substitute Decision Makers Act*, S.S. 1997, c. H-O. 001]. In Newfoundland and Nova Scotia, it is unclear whether pre-mortem transplantation optimizing interventions would fall within the scope of consent legislation.

If pre-mortem transplantation optimizing interventions were determined to fall within the scope of the legislation, the ability of a substitute decision-maker to consent to these interventions would depend on his or her knowledge. The three scenarios discussed above, for proxy consent under advance directive legislation, are repeated in most consent legislation: prior, competent, express wishes must be followed; if these are not known, the decision must be based on the values and the beliefs of the incompetent adult, and, if these are not known, the decision must be based on the incompetent adult's best interests. Again, British Columbia, Ontario, Prince

Edward Island, and the Yukon are the only jurisdictions that provide guidelines for the determination of best interests (in general, the same factors are to be considered as those under advance directive legislation).

A substitute decision-maker, therefore, could consent to pre-mortem transplantation optimizing interventions, if the incompetent adult had expressed a prior competent wish to undergo the interventions, or if, on the basis of knowledge of the incompetent adult's beliefs and values, the substitute decision-maker believes that he or she would consent to the interventions. For the reasons discussed in the previous proxy directive legislation section, it is unlikely a substitute decision-maker could give legal consent to the interventions on the basis of a best interest analysis under consent legislation.

Recommendations

Following this review of the potential consequences of the different types of pre-mortem transplantation optimizing interventions, the current Canadian practice with respect to these interventions and the legal status of consent to them, we would argue that there are a number of reasons to support a recommendation that legislation be introduced to address this consent issue.

First, the failure to provide a legal means for consent to pre-mortem transplantation optimizing interventions, through advance directives, is inconsistent with the fundamental value of respect for individual autonomy, which underlies the doctrine of informed consent. A number of individuals may well have their wishes to donate organs or tissue thwarted.

Secondly, the failure to provide a clear, legal means for consent to pre-mortem transplantation optimizing interventions, through instruction directives or through substitute decision-makers, may lead to potentially useful organs remaining unavailable and, as a result, individuals dying while on organ waitlists.

Thirdly, the uncertainties in the law will inevitably result in the interventions being performed on patients, with no consent or with insufficiently-informed consent. This is a clear violation of an individual's right to bodily integrity, and it also exposes health care providers to liability.

Fourthly, pre-mortem transplantation optimizing interventions are a reality in Canadian organ donation protocols and practices. However, if a patient is incompetent, there are significant uncertainties concerning the legal effect of consent obtained through an instruction directive or a substitute decision-maker. These uncertainties might result in considerable stress and potential liability for health care providers.

Fifthly, the legal uncertainties concerning consent to pre-mortem transplantation optimizing interventions might lead to a fear of liability on the part of health care providers. The potential liability faced by health care providers includes; criminal liability, civil liability, and professional disciplinary action. The criminal charges that health care providers could face as a consequence of failing to obtain consent to pre-mortem transplantation optimizing interventions, include assault [*Criminal Code of Canada*, R.S.C. 1985, c. C-46, s. 265] and, if the interventions cause the patient's death, acceleration of death [*Criminal Code of Canada*, R.S.C. 1985, c. C-46, s. 226], and homicide [*Criminal Code of Canada*, R.S.C. 1985, c. C-46, s. 225(1)(5)(a)]. At common law, treatment of any kind without the consent of the person being treated, amounts to battery.¹⁰ If consent to treatment is insufficiently informed, health care providers can face an action in negligence [*Reibl v. Hughes*, [1980] S.C.J. No. 105, 2 S.C.R. 880]. Finally, if a health care provider has treated a patient with no, or insufficiently-informed consent, professional disciplinary proceedings can result.¹³ Uncertain of the legal authority of the consent, some physicians might simply choose not to perform the interventions, because they do not want to risk legal ramifications. As a result, some organ donation wishes may go unfulfilled, and useful organs may be lost.

To avoid or to reduce these negative consequences, we recommend legislative reform to provide a mechanism through which patients, or their substitute decision-makers, can provide legally valid express, free, and informed consent to pre-mortem transplantation optimizing interventions where such interventions are in accordance with the wishes of the patient.⁵

Specifically, we recommend legislative reform through amendments to provincial/territorial organ and tissue donation legislation. We recommend this particular approach for a variety of reasons. Opening organ and tissue donation legislation is less controversial than opening provincial consent legislation. Organ and tissue donation legislation is specific legislation that is directly relevant to the interventions. All provinces and territories have organ and tissue donation legislation. This is not true

of consent legislation or advance directives legislation. There is also a tradition of greater consistency in organ and tissue donation legislation across jurisdictions than is found in consent legislation or advance directive legislation.

Therefore, we recommend that the following text be introduced into organ and tissue donation legislation in every province and territory in Canada:

1(1) Consent to donate organs does not imply consent to pre-mortem transplantation optimizing interventions.

1(2) A valid consent to pre-mortem transplantation optimizing interventions must be:

- (a) voluntary;
- (b) informed;
- (c) specific; and
- (d) made by a competent individual

1(3) Consent by a competent individual for pre-mortem transplantation optimizing interventions must be:

- (a) in a writing signed by the competent individual; or
- (b) orally, in the presence of at least two witnesses with contemporaneous documentation of the consent.

1(4) Consent by a substitute decision-maker for pre-mortem transplantation optimizing interventions

Where a person is incompetent and, in the opinion of a physician, the person's death is imminent, a substitute decision-maker:

- (a) must follow any prior, competent, express, free, and informed wishes of the incompetent person, with respect to pre-mortem transplantation optimizing interventions; and
- (b) if prior wishes are not known, may only consent to pre-mortem transplantation optimizing interventions if he or she believes the decision to be consistent with the beliefs and the values of the incompetent person.

Consent from a substitute decision-maker must be:

- (a) in a writing signed by the substitute decision-maker; or
- (b) orally, by the substitute decision-maker, in the presence of at least two witnesses with contemporaneous documentation of the consent; or
- (c) by telegraphic, recorded telephonic, or other recorded message of the substitute decision-maker.

1(5) Effect of consent

Consent given under subsections 1 and 2 becomes full and binding authority

- (a) when it is made; or
- (b) if it is contained in an advance directive, when the advance directive is activated.

S It must be noted here that this is not the only necessary law reform in this area. Interrelated, and similarly necessary, reform is needed for the definition and the determination of death. This, however, is the subject of another paper. See, Jocelyn Downie, Chantelle Rajotte & Alison Shea, "Legal Eligibility for Post-Mortem Organ and Tissue Donation: The Definition and Determination of Death" unpublished manuscript on file with the authors.

Conclusion

In conclusion, we return to the clear need for organs for transplantation and the understandable desire to find ways to increase organ donation and transplantation. We acknowledge that pre-mortem transplantation optimizing interventions may lead to an increase in the availability of organs and improvement in the quality of available organs. However, we urge caution in their use given the current legal framework. Clearly, where competent individuals give free and informed consent for them, they can be done. However, where incompetent individuals are involved, the legal status of substituted consent or instruction directives is frequently uncertain if not preclusive. Given the numerous benefits that could be realized by creating a framework and clinical practices within which valid consents (express, free, and informed) could be given, we conclude that reform of provincial/territorial organ and tissue donation legislation is needed. We would like to encourage physicians to take up a leadership role in respect of the law reform recommended in this paper. It is certainly in their interests to do so, for example, to reduce the risks of liability. It is also, more importantly, very much in the interests of those they care for, whether potential organ donors or recipients.

Acknowledgements

The authors sincerely thank members of the Dalhousie University Health Law Institute, Brad Abernethy, Graeme Rocker, and members of the Donation Committee of the Canadian Council for Organ and Tissue Donation and Transplantation for their helpful comments on earlier drafts of this paper. The views expressed, herein, do not necessarily represent the views of the CCOT and/or the federal, provincial, or territorial governments of Canada.

References

- 1 Dodek P. Mandatory reporting of 'imminent' death to identify organ donors: history, controversy and potential solutions. *Can J Anesth* 2003; 50: 955–60.
- 2 Bell MD. Non-heart beating organ donation: old procurement strategy – new ethical problems. *J Med Ethics* 2003; 29: 176–81.
- 3 Cook DJ, Giacomini M, Johnson N, Willms D. Life support in the intensive care unit: a qualitative investigation of technological purposes. Canadian Critical Trials Group. *CMAJ* 1999; 161: 1109–13.
- 4 Browne A, Gillett G, Tweeddale M. The ethics of elective (non-therapeutic) ventilation. *Bioethics* 2000; 14: 42–57.
- 5 Kluge EH. Elective, non-therapeutic ventilation: a reply to Browne et al. "The ethics of elective (non-therapeutic) ventilation". *Bioethics* 2000; 14: 240–7.
- 6 Browne A, Gillett G, Tweeddale M. Elective ventilation: reply to Kluge. *Bioethics* 2000; 14: 248–53.
- 7 Tregillus EV. Informed consent for trial of elective ventilation will not be forthcoming. *BMJ* 1995; 311: 1502.
- 8 Fabre J. Elective ventilation of potential organ donors. *BMJ* 1995; 311: 950.
- 9 Lewis J, Peltier J, Nelson H, et al. Development of the University of Wisconsin donation after cardiac death evaluation tool. *Prog Transplant* 2003; 13: 265–73.
- 10 Peppin P. Informed consent. In: Downie J, Caulfield T, Flood CM (Eds). *Canadian Health Law and Policy*, 3rd ed. Markham: LexisNexis Canada Inc., 2007.
- 11 Picard EI, Robertson GB. *Legal Liability of Doctors and Hospitals in Canada*, 3rd ed. Scarborough: Carswell Publishing; 1996.
- 12 Sniderman B, Irvine JC, Osbourne PH. *Canadian Medical Law: An Introduction for Physicians, Nurses and Other Health Care Professionals*, 3rd ed. Scarborough: Carswell Publishing; 2003.
- 13 Wildeman S, Downie J. Genetic and metabolic screening of newborns: must health care providers seek explicit parental consent? *Health Law J* 2001; 9: 61–111.
- 14 Rozovsky LE. *The Canadian Law of Consent to Treatment*, 3rd ed. Markham: LexisNexis Canada Inc.; 2003.