THE PRESUMED CONSENT APPROACH TO ORGAN DONATION

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INTRODUCTION

This document provides a short analysis of the issue of presumed consent as it relates to organ donation. It provides a description of this approach as well as its alternative (required or explicit consent), discusses the jurisdictional authority over consent in Canada, lists some of the experiences in other countries in this regard and offers a review of previous relevant legislative attempts both federally and provincially in Canada.

CONSENT TO DONATE: PRESumed VERSUS EXPLICIT

A. Description

Canada’s “deceased donation rate” is lower than that of many of the countries to which it is compared. International comparisons of deceased organ donor rates usually include Spain and the United States (U.S.A.), whose donor rates are reportedly 35 and 26 donors per million population (PMP) respectively. Overall, Canada ranked 20th in 2012, at about 16 donors PMP for deceased organ donor rates among the 75 countries that were surveyed.1

Figure 1 – Donor Rates in Various Jurisdictions (2012 data)


1 Information about USA and Spanish donation rates are 2012 statistics from Global Observatory on Donation and Transplantation, Organ donation and Transplantation Activities 2012, Report prepared for Government of Spain, Ministry of Health and Social Policies, and World Health Organization, slide 13 (ignore log in).
It is important to note that the term “donor” is defined differently in the U.S.A. and Spain than it is in Canada. Whereas Canada’s donor rate refers only to deceased individuals from whom at least one organ was retrieved and successfully transplanted into a patient, the U.S.A. and Spain both consider donors to be deceased persons who have been identified as potential donors but includes those whose organs may not have been transplanted. This discrepancy in donor definition inflates the U.S.A. and Spanish statistics relative to the Canadian ones. The Canadian Institute for Health Information, under its Canadian Organ Replacement Register, provides data on “referred donors,” “potential donors” as well as “actual donors.” Canada’s deceased donor rate reflects only “actual donors.”

An option often suggested as a way to increase donor rate is to implement presumed consent, sometimes called the opt-out system. Under this approach, consent to donate is presumed unless a person has expressly indicated otherwise during his or her lifetime. Canada operates under an explicit consent system (also referred to as required consent or explicit consent) whereby individuals express the intention while they are alive to become a donor upon their death. However, failure to express a desire to donate during one’s lifetime is not necessarily deemed a refusal to become a donor. Under most circumstances, the family becomes the ultimate source for consent.

B. The Debate

Proponents of the presumed consent approach note that the vast majority of Canadians are in favour of organ donation when polled, but that only a small percentage of them actually fill out their donation cards. Additionally, proponents suggest that there is no legal requirement to either solicit or respect the wishes of family if consent to donate had been provided by the potential donor. Opponents of presumed consent insist that it is not the method of consent that affects donor rate but rather the supporting donation and transplantation infrastructure that brings about increased donation rates. They also suggest that regardless of the legal requirements, family wishes will continue to be determinative in this country and that imposing a presumed consent system would not be received well in Canada. Below is an overview of some of the main issues of contention in the debate about presumed consent, which may explain, in part, why an explicit consent approach to organ donation is in place in Canada.

C. Growing Waiting Lists for Organ Transplants

In Canada as well as in all countries with transplant facilities, the number of people awaiting organ transplants is greater than the number of organs available for transplant. Proponents of the presumed consent approach state that the number of deceased organ donors will inevitably increase if there is a presumption of consent to donate. It should be emphasized, however, that even the theoretical increase is not as large as most people assume because, for a variety of reasons, few people are considered as potential donors upon death. Although the criteria are now broader than they have been in the past, essentially donor candidates are limited to those who die of stroke or heart attack and those who are victims of incidents like car accidents and gun violence. Even then, only a portion of the individuals who fall into these categories are considered. Candidates must be considered to have been generally in good health, up until the fatal event. As such, despite the theoretical pool of the entire population under a presumed consent system, only a small fraction of it becomes a candidate for organ donation.

For more discussion on organ donation and increasing the donor rate, please refer to Sonya Norris, *Organ Donation and Transplantation in Canada*, Publication No. 2011-113-E, Parliamentary Information and Research Service, Library of Parliament, Ottawa, 10 November 2011. A revised version of the publication will be available shortly.

D. Public Support for Organ Donation

Proponents of the presumed consent approach note that the vast majority of Canadians are in favour of organ donation when asked, but that only a small percentage of them actually fill out their donor cards. This phenomenon is common in other countries as well. Supporters of presumed consent suggest that potential donors are not being pursued because few have expressed in writing their desire to become donors regardless of their support for donation. The supporters suggest that implementing a presumed consent approach is consistent with the strong public support for donation and that individuals who do not wish to participate may withdraw from the system. Opponents of the opt-out system point out that countries with high donor rates, such as the U.S.A. (opt-in system) and Spain (opt-out system) are able to reach almost the same level of consent to donate from the families of potential donors. Spain has a 90% consent rate from families and the U.S.A. has a 75% consent rate.

E. Informed Consent and Altruism

Opponents of the presumed consent approach assert that it contravenes the tradition of obtaining informed consent for medical procedures. They emphasize that individuals who may have never given any thought to organ donation could still become donors, and as such were deprived of making an informed choice on the issue. In addition, opponents claim that deceased organ donation, like living organ donation and blood donation, is based on altruism, sometimes called voluntary beneficence, and that presumed consent would fundamentally change this focus.

F. Family Wishes

Many jurisdictions ultimately rely on the consent of family for organ donation. Jurisdictions with an explicit consent system may override a person’s stated will to donate should his or her family refuse to consent at the time of potential donation. Similarly, in many of the countries where legislation has been passed to implement a presumed consent system, including Italy and France (as well as Spain, the best performer in terms of deceased organ donor rates), in practice, donation does not proceed without the informed consent of family. The observation that family consent usually determines whether donation proceeds illustrates that presumed consent laws are rarely enforced.

Jocelyn Downie, a health law scholar, has argued that families have no legal authority in Canada to oppose a family member’s valid consent to post-mortem donation, except in Manitoba and Quebec. Despite this situation, she notes that studies indicate that physicians generally assume that families’ wishes would be respected over those of the donor. Further, she suggests that health care workers’ lack of understanding of the law, their concern for the feelings of family members, and a fear of lawsuits might account for this tendency to override valid consent.

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5 Donate Life California, Presumed Consent.
6 Swiss National Advisory Commission on Biomedical Ethics, On presumed consent to organ donation-Ethical considerations, 2012.
8 Ibid., p. 612.
G. Health Care System Infrastructure

Opponents of the presumed consent system argue that donation rate is a reflection of the healthcare system in general, and the transplantation system specifically, rather than a reflection of the type of consent used. This relates to health expenditures and gross domestic product, which researchers have established are associated with donor rates. Opponents of presumed consent also point to the fact that jurisdictions operating under that system have donation rates that range from a high in Spain of 35 deceased PMP to a low in Greece of 7.3 PMP (2011 rates). This disparity is evident when donation rates of presumed consent nations are compared to donation rates of required consent countries. Both groups show a wide range of donation rates and rates tend to be higher in wealthier countries that have higher health expenditures. A noted exception to this observation is the performance of Japan, a required consent country. In that country, there is a negative attitude towards transplantation that is attributed to such issues as views on death, skepticism of the criteria used to determine death with respect to organ donation, resistance to western medicine, etc. Japan’s healthcare system is similarly unprepared to undertake organ donation and transplantation at levels seen in other wealthy countries. Centres do not all have the necessary equipment or properly trained professionals to recruit donors or to conduct procedures.

H. Public Awareness and Trust

Spain has enjoyed high deceased organ donor rates for many years, during which time there has been a presumed consent approach to donation. However, donor rates initially remained stagnant in Spain following the implementation of presumed consent in 1979. It was not until the Spanish government dedicated resources not only to the donation and transplantation system so that centres had the capacity to identify potential donors, approach family in the most appropriate way, efficiently identify potential recipients and successfully conduct transplants, but also to a comprehensive public awareness campaign, that donor rates climbed. In this way, the public became aware of the issue, gained trust in the system, became more comfortable with the concept of becoming a potential donor and initiated discussions with family about their wishes.

THE APPROACHES OF OTHER COUNTRIES

Several countries have adopted the presumed consent approach (a 2012 article on the role of next-of-kin authority provides a list of 54 countries and whether each operates under an explicit or presumed consent model for deceased organ donation). A 2006 study reported that there is no direct correlation between organ donor rates and presumed consent, but suggested that after allowing for other

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10 Donate Life California, Presumed Consent.
determinants, there may be some advantage gained by such an approach. Although presumed consent is the approach used in Spain, the country with the highest reported organ donor rate, several other countries that have also adopted that approach have donor rates that are far lower than countries that operate an explicit consent system. For example, Poland and Sweden, which both operate presumed consent systems, report lower donor rates than does Canada. The U.S.A., United Kingdom (U.K.) and Ireland, which are among the countries with relatively high donor rates, have required consent systems. The same observations were reported by the Global Observatory on Donation and Transplantation in 2012.

Other common-law countries to which Canada is often compared in the development of legislative and policy initiatives include the U.S.A., the U.K., Australia and New Zealand. All of these countries operate under an explicit consent model for organ donation. This may be consistent with an argument forwarded in 2006 in the U.S.A. by the Committee on Increasing Rates of Organ Donation that presumed consent is unpopular in countries where personal autonomy is highly valued. The right to self-determination with respect to one’s body and the right to refuse medical treatment have long been carefully protected common-law principles. In Canada particularly, personal autonomy in all medical decisions is a feature of our health, or medical, legislation.

JURISDICTIONAL AUTHORITY OVER ORGAN DONATION AND TRANSPLANTATION IN CANADA

The division of federal and provincial powers with respect to health in Canada prevents Parliament from imposing consent legislation with respect to organ donation. Organ donation and transplantation legislation in Canada is largely provincial or territorial. Each province and territory has legislation in place governing donation and transplantation activities, including consent, and in all cases consent must be explicit for organ donation.

A. Constitutional Division of Powers

Jurisdiction over health is not assigned to a single level of government; some aspects of health fall under federal jurisdiction, while others fall under provincial jurisdiction. The Constitution Act, 1867 sets out several areas of jurisdiction (also known as heads of power) relevant in the health context, including:

- section 91(27): criminal law;
- sections 91(1A) and 91(3): federal spending power; and
- section 91: peace, order and good government (POGG) power.

Many areas of health, particularly health care delivery, fall under provincial jurisdiction. The relevant provincial heads of power include the following:

- section 92(7): the establishment, maintenance, and management of hospitals;

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20 Ibid.
21 Only the safety of donated organs and tissues is regulated federally. This is done under the Safety of Human Cells, Tissues and Organs for Transplantation Regulations pursuant to the Food and Drugs Act.
• section 92(13): property and civil rights in the province; and
• section 92(16): all matters of a merely local or private nature in the province.

Courts have interpreted section 92(7) as allowing the provinces to legislate in the area of hospital care, but also health care delivery more broadly. Under section 92(13), provinces have authority over “property and civil rights in the province,” which covers matters such as health insurance and the regulation of health care professionals. Finally, section 92(16) grants provinces legislative authority over “matters of a merely local or private nature in the province,” which courts have interpreted as allowing provinces to legislate with respect to certain public health matters.

1. **Criminal Law Power**

The criminal law power is used in many areas of federal jurisdiction over health. It is the authority upon which the *Criminal Code* was enacted. The *Criminal Code* does not include any offences related to organ donation or retrieval. Although s. 182(b) of the *Criminal Code* prohibits interference with and mutilation of dead bodies, this section has not been invoked in the context of organ retrieval, and if it were, it is unlikely that it would result in a finding of criminal liability.

For a court to find that Parliament has enacted valid health legislation based on its criminal law power, the legislation must address a “public health evil.”

[T]he criminal law power may validly be used to safeguard the public from any injurious or undesirable effect. The scope of the federal power to create criminal legislation with respect to health matters is broad, and is circumscribed only by the requirements that the legislation must contain a prohibition accompanied by a penal sanction and must be directed at a legitimate public health evil.

In her analysis of cases in which the Supreme Court of Canada upheld federal laws on the basis that they addressed a public health evil, Chief Justice Beverly McLachlin identified the following three features: “(1) human conduct (2) that has an injurious or undesirable effect (3) on the health of members of the public.”

2. **Spending Power**

The federal spending power is inferred from two subsections of section 91 of the Constitution: section 91(A), “the public debt and property,” and section 91(3), “the raising of money by any mode or

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22 *Schneider v. The Queen*, [1982] 2 SCR 112 [Schneider].
24 Schneider.
25 For a recent discussion of the criminal law power in the health context, please see Canada (Attorney General) v. PHS Community Services Society, 2011 SCC 44.
28 Ibid.
system of taxation.” Pursuant to its spending power, however, Parliament may create a grant for the provinces and attach any conditions to such a grant that it sees fit. Leading constitutional scholar Peter Hogg explains as follows:

[T]he federal Parliament may spend or lend its funds to any government or institution or individual it chooses, for any purpose it chooses and that it may attach to any grant or loan any conditions it chooses, including conditions it could not directly legislate. … There is no compelling reason to confine spending or lending or contracting within the limits of legislative power, because in those functions the government is not purporting to exercise any peculiarly governmental authority over its subjects.\(^{30}\)

3. **Peace, Order and Good Government**

The “peace, order, and good government” power is found in the opening text of section 91. The Supreme Court of Canada has held that this power allows the federal government to enact laws on public health in relation to issues “of national concern” that are beyond the scope of a single province.\(^{31}\) This test is considered to be a high standard, to the extent that if a given province failed to address the issue, there would be repercussions for other provinces.\(^{32}\) This power is not relied upon as frequently in the health context as the two other federal powers discussed above.

4. **Federal or Provincial Jurisdiction?**

Legal authorities writing on organ donation generally assert that organ donation falls under provincial jurisdiction.\(^{33}\) It does not appear that Canadian courts have addressed this issue directly, so it is difficult to determine whether the basis for provincial jurisdiction is related to their legislative authority over matters related to health care delivery or to property and civil rights in the province. The fact that all provinces and territories have enacted organ donation and consent legislation might suggest, however, that courts would tend to see the issue of organ donation as one that falls under provincial jurisdiction.

B. **Possible Legislative Option**

Although legislation regulating organ donation might face jurisdictional challenges, there may be a legislative option available. Pursuant to its spending power, Parliament might adopt an approach similar to that it used with the *Federal Framework for Suicide Prevention Act*.\(^{34}\) This Act could have encountered constitutional challenges if it had purported to exercise authority over mental health care delivery. In fact, the Act calls only for action on the part of the federal government and consultation with the provinces and so likely would not be considered by courts to be outside of federal jurisdiction. The Act calls for many actions that might be useful in organ donation, for example:

- providing guidelines to improve public awareness and knowledge;
- disseminating information, including information about prevention;

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\(^{30}\) Hogg, pp. 6-18–6-19.


\(^{32}\) See generally *Hydro-Québec*.

\(^{33}\) See for example Ammann (2010), p. 15.

• making publically available existing statistics and related risk factors;
• promoting collaboration and knowledge exchange across domains, sectors, regions and jurisdictions;
• defining best practices; and,
• promoting the use of research and evidence-based practices.\(^{35}\)

**LEGISLATIVE INITIATIVES**

A search of the bills that have been tabled since the 36\(^{th}\) Parliament revealed none pertaining to consent for organ donation. Additionally, there are no bills currently before any provincial or territorial legislature that propose to implement a presumed consent approach to organ donation. A media search revealed, however, that at least two provinces, Ontario and Nova Scotia, have raised the issue for debate. In Ontario a bill was introduced in 2008 on the subject, however it was not voted on during that legislative session and has not been reintroduced. Rather, the issue was referred to a committee that found the current system of consent to donate should be retained.\(^{36}\) According to news reports, in April of this year, the Minister of Health in Nova Scotia indicated that a public consultation would be launched on the issue of presumed consent.\(^{37}\) However, there is no indication on the Nova Scotia Department of Health website that such a consultation has been initiated.

**CONCLUSION**

Presumed consent may increase rates of donation once other determinants of donation have been accounted for, such as family consent and effective identification of donors within the health care setting, but most analysts agree that it cannot be implemented on its own and be expected to increase donor rates. Once other factors have been adequately addressed, such as awareness campaigns that reinforce the need to voice one’s intentions to family, and professional awareness and training programs that ensure donor identification and recruitment are done under a specific set of guidelines and policies, then further benefit might be gained from a presumed consent system. As stated in a 2012 article that compared explicit and presumed consent countries, “deceased donation programs are complex, affected not only by law, administration and infrastructure but also ideology and values. It is improbable that any single strategy or approach will cause a marked improvement on deceased donation rates.”\(^{38}\)

\(^{35}\) Ibid, s. 2(b).