The reality of organ donation: family consent represents a loss of patient autonomy and is a barrier to increasing donation rates

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Abstract - There are large discrepancies between how organ donation is defined legally and how it is applied in medical establishments. In practice, organ donation can result in a significant abuse of patient autonomy in both commonly used systems for organ donation. A large threat to patient autonomy is the practice of asking families to consent on a potential donor’s behalf, regardless of whether or not the donor’s wishes are known. There is no legal basis for requiring family consent, yet it has become common practice in both Ontario, with its expressed consent system requiring citizens to actively consent, and France, with its presumed consent system requiring citizens to actively refuse to consent. Allowing for family consent in either case is an abuse of patient autonomy and results in many lost opportunities for donation. France’s system also demonstrates that family refusal poses a barrier to higher organ donation rates. To improve organ donation rates, it is recommended that Ontario focuses on decreasing family refusal instead of adopting a system of presumed consent. There needs to be a stronger application of the law where family consent is only required if the deceased’s wishes are unknown, which will also allow current practices to better meet the standards of patient autonomy and informed consent.
I. Introduction

According to Ontario’s *Trillium Gift of Life Network Act*, a transplant is a medical procedure involving the removal of tissue from a human body (living or dead) and subsequent implantation into another living human body for therapeutic reasons.¹ As a medical procedure, organ donation should hold the same respect for patient rights, both legally and in practice, as other procedures do. The hallmarks of patient rights are autonomy and informed consent. Patient autonomy is the ability to have control over what medical procedures are consented to and decided upon, while informed consent is defined as a patient’s right to be sufficiently informed about medical procedures so the patient is able to make intelligent decisions based on comprehensive data.²

Theoretically, there are many ways of organizing the consent systems for obtaining organ and tissue donations. In practice, there are two that are widely used among developed nations: presumed consent (“opt-out”) and expressed consent (“opt-in”).³ A presumed consent system, as adopted by France, is one where all individuals within a country are presumed to consent to donating their organs and tissues upon their death unless they have expressed a wish not to. An expressed consent system, as adopted by Ontario, is one where citizens must formally register their consent in order to be organ donors.⁴

Organ donation has been an important topic for Ontario’s health care system over the last decade as many organizations have stressed the importance of increasing organ donations. In the year 2012, The Trillium Gift of Life Network website states that there were 1531 people on the wait list for an organ or tissue donation⁵ and only 579 donors⁶ which accounted for 1030 transplants.⁷ While this may not seem like a significant gap between donors and transplant...
recipients, it’s important to note that in 2012, 68 people in Ontario died while waiting for a donation. According to the Citizens Panel on Increasing Organ Donations, Ontario’s transplant waiting list has increased by two-thirds since 1994, meaning the Government should anticipate mounting pressure to enact policies to combat the increasing waiting list. In response to the low donation rates currently experienced in Canada, many have wondered what can be done to increase these rates in order to support the thousands waiting for surgery. The solution that is routinely offered is for Canada to switch to a system of presumed consent, similar to France. However, the right to refuse medical treatment and the right to security of your own person is fundamental to Canadian culture, thus changes to the current legislation would need to reflect these values. Would adopting a system of presumed consent be in line with Canadian values and would it fall within the legal parameters protecting patient autonomy?

II. Methods

Even though they use opposing systems, France and Ontario apply consent laws for organ donation in very similar ways, as they both allow for family consent to override previous decisions made by the donor. To determine if a system of presumed consent would benefit Ontario, the legal documents of both countries will be analyzed based on their representation of autonomy and informed consent. These legal definitions will be discussed in relation to the practical application of each law, with a focus on how family consent is able to impact the success of each system. Ontario’s organ donation procedures are governed by the Trillium Gift of Life Network Act, while patient autonomy and informed consent are outlined in the Health Care Consent Act. France’s organ donation procedures and regulations for patient autonomy and consent are governed by the Public Health Code (Code de la santé publique).
III. Overview of legal acts

There are four elements to consent in Ontario according to the *Health Care Consent Act*: it must: 1) be related to treatment, 2) be informed, 3) be voluntary, and 4) not be based on fraud. Consent is not considered voluntary if given by a person under duress. If a person is unable to consent, then a surrogate decision-maker is appointed who must fulfill all the elements of consent as the patient would have. The surrogate must make a decision for the incapable person according to any previously known wishes or interests.xiv

France’s consent laws state for a patient to be informed, a physician must provide clear, honest, and suitable information concerning the patient’s condition and the proposed treatment. Consent must be voluntary and informed. If a patient is unable to consent, then a surrogate decision-maker (*personne de confiance*) is appointed, consulted with, and will receive all information regarding the treatment. It is a legal requirement that the surrogate decision-maker is kept informed of all proceedings, but is unable to make medical decisions on a person’s behalf; the decision-maker is only to help facilitate communication and understanding between the physician and patient.xv

According to the *Trillium Gift of Life Network Act*, any person 16 years of age or older may consent to donating their tissues and organs and “consent is full authority to proceed”.xvi Upon a person’s death, their most recent consent is legally binding unless the acting physician has reason to believe that it had been withdrawn. If a person did not give consent before they die, then their next-of-kin can consent on their behalf unless they had reason to believe that the deceased person would have objected.xvii

In France, “*Le Registre National des Refus*” is a national registry where people can
document their objection to organ donation. According to the Public Health Code, before harvesting organs, physicians must consult the national registry, since it is a legally binding agreement to determine if the deceased refused donation. Organs are allowed to be harvested from individuals if the individual did not object to organ or tissue donation during their lifetime. If the physician is not aware of the deceased’s wishes, then they must contact the family to determine if the individual ever objected to organ donation.

IV. Family Consent

Family consent is the act of a family member consenting on the behalf of a potential donor. Often, potential donors have not made their wishes known to their relatives thus, the burden of deciding whether or not to donate rests with the family. From the perspective of hospitals and physicians, family refusal represents a formidable barrier to achieving higher rates of organ donation. In fact, many potential donors go unused due to the high prevalence of family refusal, as family refusal has accounted for greater than 60% of non-used donors. In Ontario, one study showed that the conversion from death by neurological criteria into organ donations ranged from 20% to 86% in different hospitals due to family refusal.

In Ontario, even if a person has registered their consent to donate, their family will be approached with the option of refusing donation regardless of the deceased’s expressed wishes. In France, family members are always asked if they would like to donate their relative’s organs.

V. Analysis of expressed consent in Ontario

Ontario has a registry where people can document their consent or objection to organ
donation; while this registry has legal value it is usually ignored in practice. The Trillium Gift of Life Network recommends that individuals always discuss the decision to donate with their family since the next-of-kin is always asked to reaffirm an individual’s wishes. The practical application of the law abuses patient autonomy by ignoring the decisions made by the potential donor while they were still capable of consenting in favour of the family’s consent.

Furthermore, when comparing Ontario’s Health Care Consent Act with the practical application of the Trillium Gift of Life Network Act, it seems highly unlikely any next-of-kin called upon to consent on a relative’s behalf would meet the criteria necessary to give consent. In Ontario, to meet the requirements for consent, relatives must be informed and give voluntary consent. The challenge for the health care system is that substantial burdens are in the way of relatives understanding the situation. For example, there is evidence suggesting that the general public does not understand brain death with one study observing that “80% of families who said “no” to donation never understood or accepted brain death”. Many refusals arise because relatives do not understand the scientific process behind organ donation and will thus refuse based on unfounded reasons. There is also evidence that suggests many people buy into the many sensationalized rumors surrounding organ donation. A recent online survey done by Donate Life America found that 29% of people believe that doctors will not try as hard to save their life if they are an organ donor and 55% of people believe that a person can recover from brain death. It is important to note however, that this lack of understanding also implies that citizens do not have a clear understanding of what organ donation entails and cannot be said to be informed. It is also questionable whether a relative would meet the complete requirements for voluntary consent; as relatives are facing an emotionally charged, distressing situation where a loved one has just died and therefore could be considered to be under duress and incapable of
In Ontario, the law states that surrogates must make decisions based on what the deceased *would have* wanted, however in some cases even though the relatives were aware that the deceased had wished to be a donor they decided otherwise. Oftentimes the relatives decide against donation because they do not want to give up control over the body. One study found the biggest reason for refusing to donate organs was to protect the body from being cut up because relatives could not stand the idea of their beloved relative not being physically whole. These reasons, while understandable, have nothing to do with protecting the autonomy of the deceased or protecting their values, instead are solely about the family’s bereavement.

Another factor that may explain why many Ontario citizens, while supportive of organ donation, forego donation on behalf of family members is that education about organ transplantation primarily focuses on the benefits of transplantation and its outcomes. Information regarding the process of organ donation is missing, leaving individuals uninformed about what they are consenting to. When faced with the reality of organ donation and the situation in which it occurs, it appears many people are hesitant to consent. In most cases, people are consenting to a treatment they know little about and whose benefits they rarely witness. When faced with the reality of the situation, many find it difficult to rely on rational thought and as a result, decisions are made based on feelings, myths, and misinformation. One study found that cognitive-based factors such as actual knowledge about donation are not as influential as non-cognitive factors such as: the desire to maintain bodily integrity, worry that signing a donor card might ‘jinx’ a person, and medical mistrust. Indeed incomplete or inaccurate information about the donation process may limit consent and many of the respondents in one study reported concerns about a possible lack of information that was not
shared or discussed with health care professionals at the hospital. A large worry is that a lot of the information that is reaching the public is inaccurate or based on myths about organ donation.

As has been mentioned previously, the majority of physicians and nurses feel compelled to ask the next-of-kin whether or not they are comfortable donating a relative’s organs. Perhaps some of the worry physicians have is due to the fact that people are not consenting to organ donation in the same way they would for other medical treatments and so consent does not seem real. The requirements for consent to organ donation are inconsistent with the regular requirements for consent, as there is no guarantee that a person consenting to organ donation has any information regarding the donation process and what it entails. Consent for other medical procedures depend on a person being aware of the procedures and related risks and benefits. Consent to post-mortem donation does not display any of the characteristics demanded of a regular expression of consent. Perhaps family consent in its entirety is a result of the less stringent requirements for informed consent. The consent given by patients does not seem as legitimate as other types of consent and so it is not treated as such by medical professionals.

VI. Analysis of presumed consent in France

In France, if a potential donor has registered an objection, the family will not be contacted and therefore the registry has legal value. However, since the French system is one of presumed consent, everyone who has not registered an objection is a donor. In practice, unless the potential donor has registered an objection, the family assumes the role of surrogate decision-maker and they are asked to consent on behalf of the potential donor. In France, one physician described the situation similarly, saying that according to the law if there is no objection by the
potential donor then organ and tissue harvesting may proceed, however it is the de facto practice that physicians always refer to the family members and their wishes.\textsuperscript{xxxvii} This means that people who would like to donate and make no effort to make their wishes known, due to the assumption that they are presumed to consent, are liable to have their decision revoked, or over-ridden, by their family. In this regard, autonomy is abused as the wishes of the deceased patient are ignored. Since France has a system of presumed consent, it is assumed that the best interests of the individual would be to donate their organs and allowing family members to deviate from this choice is, arguably, a violation of consent laws.

In terms of consent, France states that it must be voluntary and informed.\textsuperscript{xxxviii} As found in Ontario, both of these conditions are unlikely to be withheld when relatives make decisions on the deceased’s behalf. The only way for an informed decision to be made, which accurately reflects the wishes of the deceased, is for the deceased to make the decision. If the deceased’s consent is already known, then his or her wishes should be followed regardless of the family’s wishes, because to do otherwise, would be an abuse of a patient’s right to autonomy.

VII. Discussion of the impact of family consent on organ donation

Many believe that a physician’s fear of conflict with the family or legal system, combined with the inherent discomfort in harvesting the organs of a deceased individual, leads to the practice of always requiring family consent.\textsuperscript{xxxix} Indeed, it is the family who deals with the consequences of a relative’s death and they are the ones who live with the decision; but, if a person has already consented to organ donation, it does not seem legally permissible, according to current medical ethics thinking, to ignore their wishes.

It is a burden on the family to decide whether or not to donate a loved one’s organs, and
evidence shows that family members can feel guilt or remorse following their initial refusal to donate.\textsuperscript{xl} Furthermore the medical staff involved in these decisions often express their discomfort due to the personal nature of the situation.\textsuperscript{xlvi} It seems almost universal that, in practice, the relatives of a deceased individual make the final decision on organ donation. This is an abuse of patient autonomy because the wishes of the deceased are ignored and disrespected. As Den Hartogh, a Dutch ethicist and philosopher says, “if a person has made no will, on his death we dispose of his inheritance in accordance with default rules provided by the law; we would not consider asking his relatives whether he might have preferred to deviate from those rules”.\textsuperscript{xlii}

Truth be told, when the question of whether or not to donate falls upon relatives there are numerous contributing factors that affect how the decision is made. How the family is approached, what information they are given, and whether they were expecting to be asked, are all factors proven to influence whether or not a relative’s organs are donated.\textsuperscript{xliii} In Ontario, people believe if they designate themselves as an organ donor then their wishes will be followed, and as the citizen’s panel found most are shocked to learn that this is not the case. It was found to be unanimous among the people who attended the meetings that people wished for their choice to be respected upon their death.\textsuperscript{xliv}

Allowing family wishes regarding consent to supersede a patient’s wishes when a deceased’s wishes are known, is an abuse of patient autonomy since it ignores the consent already given by a person in favour of the family’s consent. If an individual’s consent has been given and if they have documented this consent in a manner that has legal standing, then it stands to reason that their consent should be legally binding. Neither Ontario nor France have laws that allow for families to make decisions on their relative’s behalf if the relative’s wishes are already known. There is no article defining a family’s right to refuse a relative’s donation and allowing
for such a right is an abuse of patient autonomy for the deceased individual. It is recommended, based on current medical ethics discourse, which stresses patient autonomy, that Ontario and France should both adopt a firmer approach to organ donation where the family’s consent is only required if the wishes of the individual are unknown.

VIII. Should Ontario switch to a system of presumed consent?

“It’s frustrating that almost 90 per cent of people say they’d be willing to accept a transplant if they needed it, but fewer than half say they have signed donor cards,” said Darwin Kealey, President and Chief Executive Officer of Trillium Gift of Life Network. “There’s an urgent need to bridge this gap and increase the number of donors in the province so that more lives can be saved.”

From a legal perspective, the ability to give or withhold consent for actions affecting one’s own body is grounded in established legal tradition. People may believe that a presumed consent system would increase donation rates, but the practical application of such a system seems to go against many of the beliefs that are the cornerstones of Ontario’s health care system. France’s presumed consent system represents a serious abuse of patient autonomy, by not requiring an active decision-making role for its citizens. Presumed consent does not require an exercise of autonomy or informed consent and is in sharp contrast to the patient rights outlined in Ontario’s Health Care Consent Act.

In fact, there is little evidence suggesting that a presumed consent system would be welcomed in Ontario. Frank Markel, a former CEO of Ontario’s Trillium Gift of Life Network, stated similarly in 2006, when he said that Ontario was not ready for presumed consent and that such a system should not be viewed as a solution for the difficulties found in the current organ
Indeed, the Citizens Panel agreed, stating that an opt-out system is “too passive a method to be a clear statement of an individual’s intent.”

One of the stronger arguments for presumed consent is that the majority of Canadians are in favour of organ donation anyway. Therefore, although support for presumed consent in Ontario is not unanimous, it is reasonable to presume that the great majority of people would want to donate their organs after their death. Thus, in the majority of cases, presumed consent would legitimately presume the true feelings of Ontarians. However, an important distinction to make is that while people are in favour of organ donation, they might not necessarily be in favour of donating their own organs or those of their relatives. There is a significant discrepancy between the number of people who express that they would be in favour of organ donation and the number of people who actually donate their organs. Obviously there is an unknown factor in the equation that results in low donation rates. Many believe this factor to be family refusal, and while this is entirely likely, it does not change the fact that individuals in favour of donating organs are not doing so. It is statistically likely that at least some of the relatives who refuse organ donation on a relative’s behalf have previously said they were in favour of organ donation and yet in an emotionally-charged moment refused to do so.

One possible explanation for this behaviour is that organ donation is not a gift, but a sacrifice. This certainly ties into the evidence stating that many relatives are uncomfortable with losing control over a relative's body and allowing them to be cut up. If this is believed, then presuming consent would violate patient autonomy as it can no longer be argued that consent is presumed because it is what people would have wanted anyway. Instead, since donation is a sacrifice, made to benefit an unknown individual, consent should always be expressly given to protect the autonomy of the deceased individual. One study argues that the process of organ
donation is similar to a sacrifice, since personal sacrifices are usually described as good deeds or gifts to others, usually at great individual expense. Organ donation certainly follows this description since the bereaved family must relinquish guardianship over the corpse of their loved one and allow organs to be removed for the potential benefit of an unknown recipient.

The belief that a simple policy change to presumed consent will dramatically increase organ donations is a myth. Studies have demonstrated that the type of system for organ procurement is rarely the most defining factor in increased rates of organ donation, with some suggesting that countries with presumed consent systems fare better because they have concentrated on improving and regulating their transplant organizations. Countries such as Spain and Italy have invested heavily in hiring more staff, training them, and improving the coordination between related organizations and personnel. Another study looking at whether presumed consent would work in the United States of America suggested that instead of changing to a presumed consent system, an improvement could be seen by enhancing the organization of organ procurement agencies and introducing a Family Support Service (as created by LifePoint in North Carolina) to help support and counsel family members. According to this study, introducing a counseling service to support families and their decision can represent a significant increase in organ donation rates.

Defenders of presumed consent argue that many countries employing presumed consent have higher donation rates, frequently citing Spain as the best example. Spain’s donation rates recently increased from 14 per million population in 1998 to 35.1 per million population in 2005. Spain currently has the world’s highest rate of organ donations and much of this success is attributed to the fact that Spain changed to a presumed consent system. A study was done to determine the reason for Spain’s success and the results proved that presumed consent had little
to do with the improvement. Instead, the study attributed Spain’s effort to improving the ethical foundation, respecting the country’s social values, and reducing the rate of family refusals. Refusal rates in Spain are the lowest in the world and deceased from 40-70% in the early 1990’s to approximately 15.2% in 2006.

IX. Conclusion

Many people do not understand the complexities around organ donation and therefore when confronted with the reality, are unable to rationally consider the facts and thus refuse donation. As a result, there needs to be more education in order to combat the irrational thought process that dominates the decision to donate. People have unrealistic views of what it means to be a donor and current education only focuses on the benefits for families receiving a donation, not the impact on those donating. Educating the public about brain-death and how organs are harvested is needed in order to alleviate public fears.

Currently, family consent is a large threat to patient autonomy. In both a presumed and expressed consent system, individuals have the opportunity to have their views known. With family consent, the decision is taken out of the individual’s hands and given to someone who may or may not know their preference. Personal autonomy is completely disregarded and even if one’s wishes are known, they may not be followed.

It is recommended, based on current medical ethics discourse, which stresses patient autonomy and informed consent as a basic right afforded to all citizens, that Ontario should retain an expressed consent system. Expressed consent represents the best fulfillment of patient autonomy by allowing individuals to control what happens to their body. Furthermore, there is little evidence stating that the majority of Ontario citizens would support a switch to presumed
consent and to focus on a policy change to presumed consent as a way to improve organ
donation rates represents a very superficial understanding of how such a system works.

It is further recommended that Ontario adopts a hard approach to organ donation
regarding family consent. If a person has registered their consent, then this consent is a legally
binding agreement and should be treated as such. Family consent should only occur in situations
where the deceased’s wishes are unknown. Results from Ontario’s Citizen’s Panel gave evidence
that Ontario would support a hard approach to donation. When informed of the practice of
allowing family members to override previous consent, the Ontario’s Citizen Panel almost
unanimously agreed that in the event of their death, if they had signed a donor card or registered
online then they would want their wishes followed. It was a widely held belief that donor cards
and registers carry weight and insure that one’s wishes are followed. After being informed
otherwise, many citizens were angry with the current system, showing that the people of Ontario
“want their wishes respected and overridden by no one”

Ontario’s current system allows individuals to register consent to be an organ donor
online without being prompted with information regarding the decision. Information should be
made available regarding organ donation when people register online. It would be beneficial for
Ontario citizens if the online registry made an effort to educate people while making the decision
to consent. This change would ensure that people receive relevant information about their
decision and its consequences, just as they would for any other medical procedure and would
therefore introduce a minimal requirement for informed consent. Prompting people, by asking if
they understand the decision they are making and the information they are receiving, would
elevate the consent for organ donation to be similar to the type of consent required by the Health
Care Consent Act.
References


Siminoff et al., 77.

Ibid., 77.

Morgan et al., 654.


France, "Code de la santé publique."

Nowenstein.

Sque et al., 140.

Nowenstein.


Siminoff et al., 71.

Ontario Ministry of Health and Long-Term Care, 3.


Ontario Ministry of Health and Long-Term Care, 75.


Mongoven, 90.

Healy, 1038.


Gil-Diaz, 259.

Ontario Ministry of Health and Long-Term Care, 3.