Pre-Mortem Interventions for the Purpose of Organ Donation: Legal Approaches to Consent

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Précis: The administration of Pre-Mortem Interventions (PMIs) to preserve the opportunity to donate, to assess the eligibility to donate, or to optimize the outcomes of donation and transplantation are controversial as they offer no direct medical benefit and include at least the possibility of harm to the still-living patient. In this article, we describe the legal analysis surrounding consent to PMIs, drawing on existing legal commentary and identifying key legal problems. We provide an overview of the approaches in several jurisdictions that have chosen to explicitly address PMIs within codified law. We then provide, as an example, a detailed exploration of how PMIs are likely to be addressed in one jurisdiction where general medical consent law applies because there is no specific legislation addressing PMIs — the province of Ontario in Canada.

1. Introduction

Pre-mortem interventions (PMIs), also referred to as ante-mortem interventions, are performed on patients before the determination of death in order to preserve or enhance the possibility of organ donation. PMIs, as we define them here, include interventions that preserve the opportunity to donate (e.g. nontherapeutic ventilation), measures to evaluate eligibility for donation (e.g. blood samples, biopsies,[1] or tests such as bronchoscopies[2]), and interventions to enhance the chances of successful transplantation (e.g. administration of heparin or pre-mortem femoral cannulation to enable rapid cold perfusion after death[3]). Because PMIs offer no medical benefit and include at least the possibility of harm to the still-living patient, questions arise as to whether and, if so, when it is ethical[4] and legal to perform them. Perimortem research on organ donors[5] raises similar issues.[6]

In most jurisdictions, the law requires consent to perform medical interventions on living patients with very few exceptions (e.g., an urgent need to proceed without consent to save a person's life). Where a patient is capable, consent is usually given by the patient him or herself (first-person consent). This is usually impossible for PMIs because patients who are potential organ donors are usually incapable due to illness or injury. In some cases, such patients may have previously formally expressed their willingness to donate organs by registering as a posthu-

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mous donor in an opt-in system for organ donation or they may have indicated their interest in donation to family members. In other cases, information about their attitude to organ donation may be unknown or unavailable. In presumed consent regimes, a patient's willingness to donate may be presumed because they have not opted out. A complicating factor arises if a patient has expressed the wish to be an organ donor while restricting end of life interventions such as resuscitation, ventilation or other measures that may be needed to preserve the option to donate.

In this article, we describe the legal analysis surrounding consent to PMIs. First, we briefly explain why we have chosen a broad definition of PMIs. Second, we explain the structure of the legal analysis of consent in relation to PMIs, drawing on existing legal commentary and identifying the key legal problems. Third, we address how various jurisdictions respond to these problems. The applicable laws vary by jurisdiction, and so it is not possible to provide a detailed analysis for each legal jurisdiction. Instead, we provide an overview of the approaches in several jurisdictions that have chosen to explicitly address PMIs within codified law (statutes or legislation). We then provide, as an example, a detailed exploration of how PMIs are likely to be addressed in one jurisdiction where general medical consent law applies because there is no specific legislation addressing PMIs – the province of Ontario in Canada.

Like others who have considered this problem in recent years, we highlight the value of legal clarity and recommend legislative reform to address legal uncertainty over consent to PMIs. At the same time, a legislative response has downsides, particularly if poor legislation creates new ambiguities or adopts an inflexible position that is difficult to change as the types of PMIs and information about their benefits and risks accumulates over time. We address these trade-offs in our conclusion.

2. Why take a broad view of pre-mortem interventions (PMIs)?

The phrases pre-mortem and antemortem interventions arise primarily in relation to specific interventions performed in the context of donation after the circulatory determination of death (DCD). These DCD-related PMIs are performed on the still-living patient after the decisions to withdraw life-sustaining therapies and to attempt posthumous organ donation have been taken, but before that withdrawal has taken place. In this context, a range of surgical (e.g., femoral cannulation) and non-surgical (e.g., administration of heparin) interventions are commonly discussed.[7]

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However, the issue of consent to nontherapeutic interventions to support organ donation is neither this narrow, nor is it new. It arose prominently in the debate over the Exeter Protocol in the UK between 1988 and 1994.[8] The Exeter Protocol involved ventilating patients who were expected to proceed imminently to brain death not for therapeutic benefit to the patients but to allow for organ donation. This practice stopped abruptly in 1994 when the UK Department of Health advised it was illegal under UK law, which required that interventions on incapable patients must be in their "best interests," then understood narrowly as restricted to clinical or medical interests.[9]

Furthermore, femoral cannulation and heparin do not exhaust the range of possible nontherapeutic interventions that could and do take place in the context of DCD. Still-living patients may undergo nontherapeutic interventions including blood tests, imaging, bronchoscopies and biopsies to evaluate their

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eligibility to donate, and the timing and location of death (i.e. the withdrawal of life-sustaining measures) are often altered to facilitate donation.

All of these interventions and modifications to standard end of life care are done to preserve the opportunity to donate, to determine eligibility to donate or to optimize eventual donation and transplantation outcomes, rather than for the therapeutic benefit of patients. They each present variations on the same underlying legal problem of consent to nontherapeutic interventions to facilitate organ donation.

Prior discussions of this issue have varied in the scope of interventions considered, but we choose to follow the UK Department of Health's 2009 approach in selecting a broad scope that includes all premortem measures taken solely to preserve the opportunity to donate, to assess eligibility to donate, or to enhance donation outcomes.[10] There are good reasons to take a broad view of PMIs. First, new types of PMIs are likely to arise over time, and it is best to prepare, as much as possible, for new research directions and clinical changes in resuscitation procedures,[11] support therapies, and interventions to enhance transplant outcomes. Second, defining a broad scope of PMIs will help to elucidate the boundary between those that are commonplace and uncontroversial, and those that raise concern from a legal consent perspective. This helps us to narrow the focus on what the underlying problems are, and why/when consent is unnecessary or implied, versus when this is not the case. Put another way, the consideration of many variants of the same problem of consenting to nontherapeutic interventions allows us to consider the boundary conditions of the various legal rules.

3. Consent to Nontherapeutic Interventions for Incapable Patients: Legal Questions

The central legal problem in relation to nontherapeutic medical interventions for incapable patients has to do with consent. Since the intervention is not performed for the medical benefit of the incapable patient but instead for the potential benefit of others, there is a risk that the interests of the patient may be overlooked or overridden. At the same time, capable people are permitted to consent to nontherapeutic interventions including participation in medical research, gestational surrogacy and the living donation of blood, gametes and some organs and tissues, among other things. A policy that excludes incapable people altogether from these nontherapeutic interventions protects them from exploitation and potential harm at the cost of exclusion from altruistic activities open to capable people. PMIs pose similar issues.

This problem has been resolved in other contexts in various ways. Canadian federal research ethics guidelines governing research in human participants stipulate that the involvement of vulnerable populations such as incapable participants is permissible with surrogate consent, but only if the inclusion of the vulnerable population is necessary to answer the scientific question, and only if the research is being carried out for the direct benefit of the participants or for those in the same population. For example, medical research on childhood illness including child participants is permissible if the scientific question cannot be answered using a less vulnerable population and if the research has a reasonable prospect of benefiting participants or other children suffering from the same condition in future.[12] Furthermore, if the research does not offer direct benefits to a participant, but only to those falling in the same class as the participant, then only research that poses minimal risk and burden is permitted.[13] "Minimal risk" refers to risks equivalent to those faced in the daily lives of the study population. Similarly, the Canadian province of Quebec states in article 21 of the Civil Code that:

> A minor or incapable adult can participate in research only if, where he is the only subject of the research, it has the potential to produce benefit to his health, or only if, in the case of research on a group, it is has the potential to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap.

This approach is not universal, and some jurisdictions prohibit substitute consent to medical research.[14]

Another example is the practice of pre-implantation genetic diagnosis on IVF-derived embryos in order to select an embryo that could later provide stem cells (from umbilical cord blood) to an ill sibling. In the UK, regulators initially prohibited this on the basis that the embryo biopsy offered some risk but no benefit to the potential child.[15] The position was reversed based on evidence regarding the medical, psychological and emotional implications for children and their families as well as safety of the technique.[16]

Sometimes the problem of nontherapeutic interventions on incapable people is resolved by resorting to courts for approval on a case-by-case basis. In various jurisdictions, the donation of organs or bone marrow by incapable people (children or adults) to their siblings has proceeded with prior court approval.[17]

The case of PMIs is an example of the same type of problem — i.e., a nontherapeutic intervention on

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one patient for the benefit of another — and both ethical and legal commentary has been published on the problem of consent to PMIs. The structure of the legal analysis is outlined below, along with the positions taken in a sample of publications reflecting Canadian, Swiss, UK, US and Australian legal perspectives.[18]

(1) Does the law require consent to PMIs?

- Some of the published legal analyses distinguish between three classes of PMIs:
  - » Interventions that were initiated for therapeutic objectives, but have become medically futile, and are continued to maintain the patient so that eligibility for and willingness to donate can be explored.
  - » Nontherapeutic interventions initiated solely to maintain patient stability so that eligibility for and willingness to donate can be explored.
  - » Nontherapeutic interventions intended to optimize the outcome of donation and transplantation and that are performed after the decision has been taken to donate.
- There is general agreement that consent is required for most PMIs that are performed after a decision to donate has been taken.
- Several authors discuss other categories of PMIs involving the continuation or initiation of nontherapeutic interventions to maintain the patient prior to determination of eligibility or willingness to donate.[19] In some jurisdictions, these other interventions may be permitted or even required without consent unless the patient is known not to wish to be a donor.[20]

(2) Does prior expression of the desire to be an organ donor constitute implied consent to PMIs?

- There is general agreement that prior expression of the wish to be a posthumous donor does not constitute implied consent to PMIs because the use of PMIs is generally unknown to the public. As a result, people expressing the wish to donate are likely to have contemplated only posthumous interventions.[21] However, some authors take the perspective that consent to non-harmful interventions should be implied by the desire to donate, since separate consent to all the specific sub-steps involved in other medical interventions is not always required.[22]

(3) Who may consent to the performance of PMIs on an incapable patient?

- There is consensus that where permitted by law, and within the limits set by the law, legally recognized surrogate decision-makers (SDMs) may consent to medical interventions to be performed on incapable patients. The law may restrict the ability of SDMs to consent to certain types of medical interventions such as PMIs however.
- In some places, the law recognizes various parties such as family members as SDMs for incapable patients. in others such as the United Kingdom, the potential treatment provider usually makes decisions for an incapable person in their best interests and relatives have no formal decision-making power unless they have been appointed under a lasting power of attorney.[23]

(4) Is the range of PMIs for which SDMs may consent restricted by the law?

- Some jurisdictions explicitly restrict the scope of the PMIs for which SDMs may give consent. In Switzerland, SDMs may not consent to PMIs that hasten death or pose a risk of permanent vegetative state. SDMs in Switzerland may only consent to PMIs that are essential for the success of transplantation and pose no more than minimal risk (the law states that femoral cannulation and mechanical cardio-pulmonary resuscitation for the purpose of donation are prohibited).[24]
- Some jurisdictions, such as New South Wales in Australia, appear to legally prohibit PMIs because SDMs are limited to consenting to measures that are in the clinical interests of patients.[25]

(5) What are the decision-making principles that must be followed by SDMs in deciding whether to consent to PMIs?

- Several authors take the position that the law is not clear on whether SDMs may consent to PMIs under the laws of their jurisdictions, and call for clarification.[26]
- Some jurisdictions direct SDMs to decide in accordance with what the patient would have wanted, although limits are placed on the scope of PMIs for which an SDM may give consent.[27]
- Some jurisdictions direct SDMs to decide in accordance with the best interests of the patient (which includes not just clinical interests but also the values and beliefs of the patient).[28] Authors diverge on how they treat patient values and beliefs in determining best interests, with one suggesting a specific desire to donate is required rather than general belief in altruism.[29] For another, a known desire to donate is

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not enough to justify a PMI because the patient's position on end of life care is unknown and may be inconsistent with donation.[30] Some take the position that an appeal to a patient's values and beliefs can only justify minimally burdensome interventions and cannot justify the administration of interventions that pose the risk of harm or distress.[31] Further, some state that if values and beliefs are unknown, it is not possible to conclude that PMIs are in the best interests of the patient.[32]

(6) What should be done if an advance directive refuses measures such as ventilation that are required to preserve the option for donation?

- An apparent conflict may arise where it is known that a person wished to donate but also refused measures that may be required to maintain the patient for the purposes of organ donation.
- This problem is addressed by the revised Uniform Anatomical Gift Act, 2006 (UAGA) in the United States,[33] which directs the attending physician to resolve this with the legally authorized SDM as expeditiously as possible. Until the conflict is resolved, measures needed to protect organs may not be withheld or withdrawn from the prospective donor unless they are contraindicated by appropriate end-of-life care.

4. Laws that Explicitly Address Consent to PMIs

A theme in the legal commentary is the need for clarification or reform of the consent laws to address issues regarding PMIs.[34] Some legal jurisdictions have enacted specific legislation addressing PMIs, which may serve to resolve uncertainty about how the general rules of medical consent apply in this specific context. In this section, we briefly review several examples of jurisdictions that have done so.

A. Nova Scotia, Canada

Canada is a federal state, and the regulation of health care falls mostly within the provincial legislative jurisdiction. The Canadian province of Nova Scotia's 2010 *Human Organ and Tissue Donation Act* required explicit consent to be given for "Pre-Death Transplant Optimizing Interventions," which are defined as "interventions that are performed on a person before the person's death for the purpose of optimizing the chances of a successful transplantation."[35] This was not changed when the province amended the statute in 2019 to enact a deemed consent system for posthumous organ donation.[36]

The law states that consent to donate organs does not imply consent to these pre-death interventions.[37] In the case of an incapable patient, the substitute-decision maker must first consult the patient's personal directive instructions and, if none are present, must decide in accordance with the patient's wishes as evidenced by their values and beliefs along with any other written or oral instructions.[38] Presently, there is no case law interpreting these statutory provisions and neither the professional colleges nor provincial health authority have released any standards, guidelines or resources on dealing with consent to pre-death transplant optimizing interventions in practice.

Prior to the shift to a deemed consent system, a person's registration as a posthumous donor would have offered some evidence regarding a patient's values and beliefs, even if it did not constitute implied consent to PMIs according to the legislation. With the shift to the deemed consent system, Nova Scotia's registry now offers three possibilities: consent, refusal or silence (which is deemed consent to donation for capable adults ordinarily resident in Nova Scotia). The failure to opt out is not as strong a source of evidence regarding values and beliefs about donation as is registered consent, as it could result from inattention or inertia. One unfortunate possible consequence of the current regime is that some people who might otherwise have registered their consent will rely upon the deemed consent provision, and the stronger evidence regarding values and beliefs will no longer be available to SDMs trying to decide whether to consent to PMIs.

The current legislation also offers little guidance on how to resolve some of other areas of legal uncertainty related to PMIs discussed above. For example, the issue of a conflict between donation and an advance directive refusing life support measures is not clearly addressed because the definition of pre-death transplant optimizing interventions is ambiguous. It appears to be restricted to measures taken to optimize transplant outcomes after the decision to donate is taken, and so may not apply to measures taken to maintain the possibility of donation prior to taking the decision to donate. As noted above, there are divergent views on what types of values and beliefs justify substitute consent to PMIs (i.e. a specific desire to donate versus general altruistic tendencies), and how to balance potential risks of PMIs against values and beliefs that support donation. These remain uncertainties under the Nova Scotia approach.

B. Scotland

Scotland's new presumed consent legislation, the *Human Tissue (Authorisation) (Scotland) Act 2019*[39]

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amends the *Human Tissue (Scotland) Act 2006* in various ways, including in relation to "pre-death procedures."[40] The new section 16A of the revised *Act* defines "pre-death procedure" as a medical procedure intended to increase the likelihood of successful transplantation and which is not for the primary purpose of safeguarding or promoting the physical or mental health of the person.[41] Regulations under the *Act* divide pre-death procedures into two classes: Type A, which are the more routine or less invasive procedures, and Type B, which are the less routine or more invasive procedures. Only those types of PDPs that are listed in the regulations as Type A or B can be performed. [42] Furthermore, they may be administered only if unlikely to cause more than minimal discomfort or harm to the patient, and if necessary to determine eligibility for transplantation or to optimize the likelihood of successful transplantation.[43]

Authorization procedures differ according to whether a pre-death procedure is Type A or B. Type A procedures are authorized by law in the case of patients who have expressly consented to donation or who are deemed to have consented to donation because they have registered neither consent nor refusal.[44] Where deemed consent does not apply, the nearest relative or parent entitled to authorize donation must authorize the procedure.[45]

As for Type B procedures, substitute consent by the patient's nearest relative is generally required.[46] The relative may consent after considering the patient's past wishes and feelings as far as reasonable and if satisfied that the patient would have been willing to undergo the procedure if capable.[47]

Type A interventions include:[48]

- Collection of bodily fluids and microbiological samples (e.g. blood, urine)
- Radiological imaging (x-ray, ultrasound, transthoracic echocardiography) without transferring the person from their existing location
- Cardiovascular monitoring (e.g. ECG, blood pressure, venous pressure, arterial line)
- Respiratory monitoring and support (e.g. sustained pre-established artificial ventilation, measuring oxygen saturation)
- Administration of certain medication or other products (IV fluids, blood and blood components, antimicrobials, drugs to manage blood pressure)

Type B interventions for which separate consent is required include:[49]

- Radiological imaging (MRI and CT scans, as well as X-ray, ultrasound, transthoracic echocardiography where the person is transferred from their existing location)
- Bronchoscopy
- Skin biopsy
- Scraping/swabbing of a body orifice (other than mouth, nostril or ear canal)

Scotland's approach illustrates the use of subordinate legislation (i.e. regulations) to specify details regarding the scope of permissible PMIs and the corresponding consent procedures. Because it is usually simpler to amend regulations than primary legislation, this approach allows for more efficient amendment of the regulatory scheme for PMIs as experience accrues and practice changes.

C. Switzerland

Switzerland has explicitly addressed consent to PMIs since the implementation of the Swiss *Federal Act on the Transplantation of Organs, Tissues and Cells* (implemented 2007) and has done so with more clarity since the Act was revised in 2015.[50] Article 10 defines "preparatory medical measures" as medical measures intended solely to preserve organs, tissues or cells."[51] If the patient is incapable, then these preparatory measures may only be administered after a decision has been taken to withdraw life support, and consent must be given by the next of kin in accordance with what they believe the patient would have wanted. If the next of kin are uncertain about the patient's wishes, they may still consent but only if the preparatory medical measures are a) essential for the successful transplant of organs, tissues or cells; and b) pose minimal risk or harm to the donor.[52] The types of measures that do not do not meet these two requirements are the placement of an arterial cannula for cold perfusion and mechanical resuscitation.[53] Under this law, when there are no next of kin available to decide for an incapable patient, preparatory medical measures cannot be administered.[54] These measures are also prohibited when they hasten the patient's death or may cause the patient to fall into a permanent vegetative state.[55]

Amendments to the federal transplantation law to move to a presumed consent system were proposed in October 2021.[56] The change was approved by referendum in May, 2022. [57] The proposed law would amend Article 10 to state that preparatory medical measures may be performed if a person has not refused to donate, and in particular they may be administered while attempts are made to determine if the person has refused to donate.[58] The proposal also indicates

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that preparatory measures can only be carried out if they a) do not accelerate the death of the donor; b) do not cause the donor to fall into a permanent vegetative state; c) present minimal risk and burden to the donor; and d) are essential for the success of the transplant.[59] A specific list of measures that do not satisfy these four conditions is to be prepared.[60] Furthermore, they may only be administered after a decision to withdraw life support.[61] The amendments of 2021 appear to remove the requirement for explicit consent to preparatory medical measures by next of kin in many cases.

D. United States

The *Uniform Anatomical Gift Act* of 2006 (an update of a 1987 uniform model law) is a model law created by the Uniform Law Commission, which is a body established in 1892 to provide states with proposed model laws on topics falling within state legislative jurisdiction.[62] To date, the UAGA has been adopted in 48 jurisdictions across the United States.[63]

The UAGA addresses PMIs in a limited way. In particular, section 14(c) provides that when a hospital refers a person at or near death to an organ procurement organization (as is required by federal laws), the organization may conduct reasonable examinations that are needed to determine donor eligibility. During this examination period, measures needed to "ensure the medical suitability of the part" may not be withdrawn unless the hospital or organ procurement organization know of a wish to the contrary. However, a general wish not to have life prolonged by life support systems does not necessarily constitute a wish to the contrary that would force the removal of life support. Rather, one of the changes brought about by the 2006 revision was a resolution to the problem arising where a patient has registered as a posthumous donor or the next of kin are authorizing organ donation but the patient also has a declaration or advance directives refusing life-sustaining interventions like ventilation that may be required to permit organ donation. Section 21 of the UAGA provides that the conflict between the two must be resolved as expeditiously as possible by the patient's SDM. Measures necessary to maintain the possibility of donation may not be withheld or withdrawn until that conflict is resolved unless contraindicated by appropriate end-of-life care. The UAGA does not direct how this conflict is to be resolved except by noting that the SDM is to "act for the donor to resolve the conflict." As noted in the commentary on the UAGA, a person could avoid the conflict by addressing their priorities clearly within a declaration or advance health-care directive.[64]

E. Summary

The scope of the legislation addressing PMIs varies considerably. The UAGA (United States) addresses life support while eligibility for donation is determined but is silent on the measures taken after a decision to donate has been taken. Nova Scotia's legislation seems the opposite, although the law is ambiguous. It refers to pre-death transplant optimizing interventions, which could be taken to mean interventions administered after the decision to donate has been taken but not measures to preserve the opportunity to donate. Scotland's law seems to contemplate a range of measures for assessing eligibility, maintaining the opportunity to donate (continuation of pre-established ventilation), and improving transplant outcomes.

Scotland and Switzerland take the useful step of clearly identifying the types of PMIs being regulated, although in different ways. Scotland permits only PMIs that are listed in regulations, while Switzerland lists only those that are prohibited. Others, like Nova Scotia, do not explain what interventions fall within the phrase "pre-death transplant optimizing interventions."

The laws also vary in how they approach consent to PMIs, with laws apparently requiring SDM consent always, sometimes or never (although situations in which consent is not needed are only those that pose minimal or no risk of harm).

Furthermore, few of the jurisdictions address the problem of inconsistency between organ donation and advance directives refusing measures necessary to maintain life pending confirmation of eligibility for and willingness to donate.

5. Case Study: Legal Analysis where the Law does not Explicitly Address Consent to PMIs

Unlike the jurisdictions mentioned above, most do not explicitly address consent to PMIs in their organ donation and transplantation laws, unlike the jurisdictions mentioned above in section 3. Of course this does not mean that there are no applicable laws. Here we explain how the legal analysis might proceed under general medical consent law using the Canadian province of Ontario as a case study. The analysis would vary for other jurisdictions whose legal structures and general medical consent laws are different.

Ontario is a common law jurisdiction with legislation addressing both organ donation and transplantation (*Gift of Life Act*[65]) and consent to health care in general (*Health Care Consent Act*, 1996[66] (HCCA)). Neither mentions PMIs specifically. As will be explained below, the HCCA likely requires consent for most if not all PMIs, and this consent will usually

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need to be given by an SDM since patients are most often incapable. On our reading of the HCCA, interventions that pose a risk of harm might be acceptable if the SDM is confident that the patient would have been willing to run that risk, based on the knowledge of that patient's values and beliefs. However, what constitutes an acceptable risk of harm is not explicitly defined in the *HCCA* nor has it been addressed in the courts. In the next few sections, we outline the legal reasoning behind this position, and we further consider the problem of advance directives that refuse measures that are necessary to preserve the opportunity to donate.

A. Are PMIs "Treatment" Under the HCCA?

The first question to be answered is whether the *HCCA* applies to PMIs. The *HCCA* provides rules for consent to "treatment." Treatment is defined in the *HCCA* as "anything that is done for a therapeutic, preventative, palliative, diagnostic, cosmetic or other health-related purpose," subject to certain exceptions.[67]

PMIs do not clearly fit within this definition, as one reasonable way to interpret it is that there may be various purposes of treatment (i.e. therapeutic, preventative, diagnostic, cosmetic etc.), but they all relate primarily to the health of the patient rather than that of third parties. The possible exclusion of PMIs from the scope of the HCCA's consent rule should not be taken to mean that no consent is required for PMIs. Instead, the common law consent rules would apply. Another way to resolve the interpretative ambiguity is to read the definition more broadly, such that the term "health-related purpose" in the *HCCA* might include interventions performed on a patient to promote the health of third parties or, more likely, the patient's interests in the health of others.

The *HCCA* also excludes certain interventions from the scope of the term "treatment" as it is used in the Act. In particular, "a treatment that in the circumstances poses little or no risk of harm to the person" is exempt from the definition of treatment.[68] This exception has received very little judicial attention,[69] but has been found to include taking blood at a hospital.[70]

Since various PMIs would pose little or no risk of harm, they might therefore be exempted from the application of the *HCCA* and its consent requirement. However, the thrust of the *HCCA* is to protect the autonomy and other health-related interests of patients. Should measures performed for the benefit of others be exempted from the *HCCA* consent regime, even if they pose only minimal risk to the patient? Again, the law leaves an uncertainty about how to handle interventions that offer no direct medical benefit to the patient, but which might fit within an extended concept of benefit that includes the ability to altruistically assist a third party.

As mentioned earlier, in the research context, SDMs may consent to research participation by incapable people, but subject to multiple restrictions where the research does not offer those people direct benefits (i.e. it must pose minimal risk, be necessary to include the vulnerable group, and offer benefits to others in the same vulnerable group). Outside the research context, courts have occasionally authorized non-therapeutic medical interventions such as bone marrow donation to a sibling.[71] These examples suggests a willingness to recognize that a person may have interests in undergoing health-care interventions that offer medical benefit only to third parties, although in the latter case court oversight rather than simple SDM consent has been required. This greater caution suggests that we should interpret the HCCA exclusion as applying only to minimal risk interventions that offer direct benefits to the patient.

In summary, there are good reasons to regard PMIs generally as "treatments" falling within the consent requirements of the *HCCA*. There remains a possibility that minimal risk interventions fall outside the *HCCA*'s consent requirements, but it is not clear that this extends to interventions performed for the medical benefit of third parties.

B. Does Consent to Donate Posthumously Include Consent to PMIs?

Any medical intervention will consist of many smaller sub-procedures, and a question arises as to whether general consent covers all of the included sub-procedures. As Robertson and Picard state, it is likely that the various sub-procedures which form a "necessary or usual part of the treatment" would be covered by the general consent to the treatment.[72] This recognizes that it would be impractical and burdensome to demand separate informed consent at too granular level of detail. If the essential of informed consent is that a patient understand the overall risks and benefits of the treatment and its alternatives,[73] one can see that detailed discussion of sub-procedures may not needed. At the same time, if there are likely limits to this, particularly if unusual, additional, or potentially risky sub-procedures have not been disclosed to the patient.

How should this line of reasoning apply in the context of PMIs? Should PMIs be understood as necessary and usual sub-procedures of posthumous organ donation, such that consent to organ donation would cover consent to PMIs? The difficulty is that

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most organ donors receive little to no information about PMIs when they register to donate,[74] and they likely think that in registering they are consenting to things that will take place after their deaths.[75] It seems strained to subsume consent to PMIs, particularly those posing more than minimal risk, within consent to a posthumous intervention like organ removal. Another problem is that valid consent under the *HCCA* must be informed,[76] and the average person's expression of willingness to donate organs is not particularly informed regarding any of the processes of organ donation. As a result, there is no adequate informed consent to an overarching procedure that might be taken to include consent to a range of necessary and usual sub-procedures. In fact, one of the reasons why the willingness to donate posthumously does not require informed consent is that it governs actions after death, not before. All of this makes it difficult to argue that a patient's expressed willingness to donate posthumously should be taken to include consent to PMIs. It is true that capable and applicable advance directives should be respected even if they were not informed,[77] and so it could be said that the desire to donate — including PMIs — should be respected even if it was not informed. However, an important distinction between advance directives and registration to donate organs is that it is more reasonable to assume a person has contemplated some of the risks of premortem care when completing an advance directive than when registering for posthumous organ donation.

The same logic arguably applies with respect to SDMs who are approached to consent to organ donation on behalf of a family member who has not registered, or to confirm authorization on behalf of a family member who has registered. They too — like other lay members of the public — will not necessarily understand what PMIs are involved and it is difficult to understand their authorization of donation as encompassing PMIs.

At the same time, most of the public is unaware of all the steps of a complex medical procedure, and it would be unreasonably burdensome to require explicit consent to each step. As a result, various steps are routinely treated as falling within overarching consent to the main intervention. Scotland presumes consent to certain low risk PMIs that are contained in its Type A list of procedures.[78] This may reflect the fact that they are low-risk and it is considered reasonable not to insist on explicit consent to them. Furthermore, many of the Type A procedures are those which would be included in routine ICU care, and explicit consent is not currently sought.

C. Can substitute Decision-Makers Consent to PMIs?

The *HCCA* sets out the principles according to which an SDM may give consent on behalf of an incapable person. If there is a known wish applicable in the circumstances, expressed by the incapable person while capable and after attaining the age of 16, then the SDM must give or refuse consent in accordance with that wish.[79] If there is no such wish known, then the SDM must act in accordance with the best interests of the patient, and the *HCCA* lists what matters should be considered in judging the patient's best interests. These include the values and beliefs that the incapable person had while capable and that the SDM believes the person would act upon if they were capable, as well as impact on the patient's condition or well-being of the treatment or its alternatives.[80]

Does a known desire to donate count as a "wish applicable to the circumstances?"

Under the *HCCA*, an SDM must follow a prior capable wish that is applicable in the circumstances. This has been interpreted to require that the patient had previously considered the *particular* circumstances they are *currently in* and made *clear directions* in relation to those circumstances.[81] The Supreme Court of Canada has also clarified that changes in a patient's condition, prognosis and treatment options can affect the applicability of a prior wish, and a wish that is unclear, vague or lacks precision may be found inapplicable to the circumstances.[82]

As a result, the desire to donate is unlikely to count as an expressed wish to undergo PMIs because it is not sufficiently specific. For a prior wish to satisfy this part of the *HCCA*, it seems to us that the patient would have to have expressed at least a wish to undergo PMIs in general to enhance organ donation outcomes if not a wish in relation to specific procedures themselves if they are higher risk. If this requirement is satisfied, a known desire to receive PMIs would likely count as a wish applicable to the circumstances. In most cases, it will likely be difficult for an SDM to show the patient expressed a wish specific enough to be applicable.

Would PMIs be in the best interests of the patient?

The *HCCA* indicates that a judgment of the patient's best interests should consider several components. First, the SDM must assess the values and beliefs of the incapable person.[83] Incapable people include those who were capable but lost capacity due to illness or injury, as well as people who were never capable, such as children or adults with intellectual disabilities. Determining the values and beliefs of people who were never capable poses special concerns. In the context of

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living organ and tissue donation by children to their siblings, some courts have allowed parents to consent on behalf of their incapable children,[84] while others have refused to permit it.[85] Nevertheless, cases allowing living donation by incapable children suggest that a substantial level of risk could be justified on the basis of social and familial interests. The involvement of the courts in these cases points to concern with permitting SDMs alone to make such decisions, at least with respect to invasive living donation. Many PMIs are lower risk, but they do not offer the ongoing relational benefits that have occasionally been taken to justify living donation by incapable people to their family members. Instead, the benefits of successful donation have to do with leaving an altruistic legacy.

It is important to note that excluding incapable persons from participating in more broadly altruistic gestures removes an option open to others. Ultimately, a balance must be struck between the risk of suffering and exploitation through harmful PMIs and the risk of exclusion from the social benefits of donation (e.g. leaving a legacy, participation in an important social system of solidarity and altruism). The law does not provide clear directions on how to do this.

Values and beliefs are not the only things that an SDM must consider in determining what is in the patient's best interests. The *HCCA* directs the SDM to consider any expressed wishes that did not satisfy the statutory requirements (e.g. age, capacity, practical possibility) and so were not binding.[86] And, finally, the SDM must consider the impact of the treatment on the patient's condition or well-being, whether the benefit of the treatment outweighs the harms, and whether a less intrusive/restrictive treatment would be as beneficial.[87]

The courts have discussed the meaning of the statutory terms "condition or well-being," finding that they encompass not just preservation of life and physical health but also extend to quality of life matters such as dignity and discomfort. PMIs are unlikely to improve the general physical condition of the dying patient, but they may minimize damage and dysfunction to transplantable organs.[88] However, it is difficult to interpret the protection of isolated transplantable organs as a benefit to the person's condition or well-being, which appear to be broader holistic concepts. An argument could be made that administering PMIs would allow more time for a prognosis to be made, which may result in some patients surviving. Manara *et al* caution against the early withdrawal of life-sustaining therapy (WLST) and discuss five patients who were admitted to the ICU with a devastating brain injury but survived because WLST was delayed in response to organ donation preparation.[89] Some PMIs like ventilation may therefore offer a benefit of this type to patients where there is a reasonable chance of survival. However, ventilation also raises the possibility of survival with severe disabilities like a permanent vegetative state, which would not be considered a benefit by everyone.

As for the impact of PMIs on aspects of well-being like dignity or discomfort, there are no psychological or experiential benefits or harms to an unconscious patient. However, some argue that PMIs may confer non-physical benefits or harms of other types for unconscious patients.[90] Benefits might include an improved chance to create a legacy of donation, perhaps alleviating the grief of bereaved family members and helping recipients. Harms might include prolongation and medicalization of death and indignity.

In the context of continued treatment of people in a permanent vegetative state, the courts have tended to accept that people who are unconscious can still suffer dignitary harms despite being unaware of them.[91] Since dignitary harms flowing from medical intervention are recognized for unconscious patients, it stands to reason that an unconscious patient might also have an interest in benefits like an improved chance of leaving a legacy of successful donation. An example of an English case supporting this idea is *ITW v Z and Others*,[92] which dealt with the interpretation of the phrase "best interests" in the context of a dispute over a will. In the course of his reasons, Justice Munby observed that:

> Best interests do not cease at the moment of death. We have an interest in how our bodies are disposed of after death, whether by burial, cremation or donation for medical research. We have, as Lewison J rightly observed, an interest in how we will be remembered, whether on a tombstone or through the medium of a will or in any other way. In particular, as he points out, we have an interest in being remembered as having done the "right thing", either in life or, *post mortem*, by will.[93]

Nova Scotia's PMI legislation explicitly states that the psychological, emotional and social well-being of the donor is to be considered,[94] and UK law has been increasingly taking a holistic view of best interests including ethical, social, moral and welfare considerations.[95]

Although legislation and decisions outside Ontario do not bind the Ontario courts in their interpretation of the *HCCA*, it is likely that the non-physical benefits of PMIs would be recognized as part of "well-being."

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In fact, Ontario courts have interpreted "well-being" as including dignity, quality of life, happiness, contentment, prosperity and good health.[96]

At the same time, this type of thinking opens the door to the risk of instrumentalizing a still-living patient for the benefit of others by re-conceptualizing an intervention as a benefit to that patient. Care must therefore be taken with respect to how far this should go and how to balance interests in a dignified and peaceful death against the potential benefit to one's legacy.

In summary, the *HCCA* is likely to accept that PMIs could be in the best interests of a dying patient in several ways. A patient's values and beliefs might support their use, with a caveat regarding using this concept to justify higher risk PMIs for patients who had never been capable. A PMI that offers a reasonable balance between harms to quality of life (including dignitarian interests of unconscious patients) and the possible benefits of leaving a legacy could also be viewed as being in a patient's best interests.

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D. Does Continuation of Treatment Past the Point of Therapeutic Effect Require Consent?

A separate consent problem has to do with the shift in the objective of an intervention from a therapeutic objective to another objective such as organ donation. Would consent to the therapeutic objective continue to provide sufficient consent for its continuation for nontherapeutic reasons?

In a typical case that could lead to organ donation, ventilation and other life-sustaining measures would be applied on an emergency basis following serious brain injury to try to save the patient and to allow time for prognosis to be assessed. This does not pose concern from the perspective of consent, since the *HCCA* presumes consent to treatment in an emergency for an incapable person as long as there are no grounds to believe the person made a valid prior refusal of that treatment.[97] It may be continued as long as is necessary to find the SDM and to secure consent.[98]

Continued life support is often maintained past the point that recovery has become highly unlikely. This is done to allow the family to gather to make decisions about withdrawal of life-sustaining therapy, to say goodbye, to assess medical eligibility for organ donation, to allow for inquiries into willingness to donate organs, and to leave time to prepare for donation where authorization has been granted. A question arises as to whether consent to continue this nontherapeutic life support is required. In Ontario, the Supreme Court of Canada has ruled — based on a technical parsing of the HCCA - that consent is required to withdraw life support such as ventilation.[99] This would settle the issue in Ontario from the practical perspective, at least until an SDM can be consulted. We nevertheless go on to consider the matter of whether consent is required to continue nontherapeutic interventions, as it might arise in similar jurisdictions where courts have not issued such a ruling.

The *HCCA* contemplates the issue of whether separate consent is required when an ongoing treatment changes. As long as the nature, expected benefits, material risks and material side effects are not significantly different from the original treatment, consent is presumed to include a) variations or adjustments in the treatment, or b) the continuation of the same treatment in a different setting.[100]

It is not clear that continued ventilation for the purpose of organ donation would fit within this exception. One could argue that the objective of a treatment is part of its nature and so ventilation for organ donation may be viewed as different from therapeutic ventilation. The risks of ventilation include entering a permanent vegetative state, but the possible benefits of continued ventilation are likely very different once there is no chance of medical improvement and other donation-related objectives are being pursued. In the

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Spanish program of Intensive Care to facilitate Organ Donation (ICOD),[101] ventilation is continued in the expectation that a patient will proceed to brain death and so be eligible for donation after a neurological determination of death. The Spanish program suggests that this should only be done in patients who are expected to proceed to brain death relatively soon.[102] Under the Ontario law, this strikes us as quite different in "nature" from therapeutic ventilation and so would likely require informed consent. Indeed, the Spanish program does contemplate securing family consent to the use of nontherapeutic ventilation in this way.[103]

Scotland's new legislation addresses pre-established ventilation directly. It includes "sustaining the appropriate operation of any pre-established airway and ventilatory support" in the list of Type A procedures not requiring additional consent.[104] Similarly, scholars in the UK have opined that continuing extracorporeal membrane oxygenation (ECMO) (i.e. a mechanical pump that does the work of the heart and lungs for a patient) in patients already on ECMO would raise little concern, but putting a patient on ECMO for the sole purpose of preserving organs would require specific consent due to its invasive and risky nature.[105]

As a practical matter, continuing pre-established interventions past the point of therapeutic effect to maintain a patient until willingness to donate has been ascertained is practically necessary and seems reasonable. If the *HCCA* were interpreted to prevent this, it would have the effect of foreclosing the option to donate in many cases. It would also be inconsistent with other case law holding that under Ontario's *HCCA* substitute consent is required for the withdrawal of ventilation.[106] As a result, it seems reasonable to conclude that pre-established interventions may be continued at least until an SDM has been consulted about donation, particularly where that continued intervention poses little additional risk to the patient and no prior refusal of ventilation by the patient has come to light.

E. Should an Advance Directive be Disregarded for a Person Known to be Willing to Donate Organs?

Another set of consent-related problems arise where a do not resuscitate order or an advance directive refusing measures like ventilation exists. First, should measures necessary to preserve the donation opportunity be administered until the patient's wishes regarding organ donation become known? Second, if a patient is known to have wanted to donate, how should this be reconciled with the refusal of measures that may be necessary to preserve the opportunity for donation?

Ontario law does not clearly address this situation. Under the *HCCA*, a treatment may not be administered if a physician has reasonable grounds to believe that the person expressed a wish applicable in the circumstances to refuse that treatment.[107] One solution to the quandary would be to interpret a refusal of life-sustaining measures as *inapplicable* in the circumstances where a patient is a potential organ donor. The courts and tribunals have emphasized that prior capable wishes should not be applied mechanically or literally without regard to changed circumstances.[108] Changes in a patient's condition, prognosis and treatment options may all affect the judgment of whether the prior wish is applicable in the current circumstances.[109] The proposed interpretation would therefore be that the rare opportunity to donate constitutes a change in options and circumstances that would likely not have been contemplated at the time a person completed an advance directives refusing resuscitation and ventilation. This interpretation also relies on the further assumption that most people would want the opportunity to donate to be preserved until the possibility of donation is ruled out. These assumptions will not necessarily be correct for everyone, and whether there is room to interpret the advance directive in this way would probably depend upon the wording of the directive and the circumstances of the case.

A contrary argument would be that medical decisions are supposed to be made independent of the possibility of organ donation. This is to ensure that all appropriate efforts are taken to save the patient and physicians do not abandon efforts too early because they contemplate the potential benefit of organ donation. The situation being discussed here is the inverse – for some, unwanted care might be provided because of the possibility of organ donation.

In an emergency, the medical team is likely to resuscitate a patient and start ventilation where it is medically indicated, unless they are aware of a DNR or advance directive expressing contrary wishes. In most cases, the eligibility for and willingness to donate will be unknown at the point when these interventions must be applied. In the rare cases where the patient is known to be a willing donor, there is a difficult tension to resolve, and there is little time to consult an SDM to try to resolve it. In some jurisdictions, medical teams will follow a clear advance directive refusing life-sustaining measures even if patient is a willing donor. In the US, the UAGA resolves the problem by stating that until the medical team can resolve the conflict with the SDM, measures needed to preserve the donation opportunity must be administered.[110] The UAGA unfortunately does not go on to explain how the conflict is to be resolved. It seems reasonable for an SDM to consider the two apparently inconsistent wishes

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and attempt to resolve them in a way that allows for organ donation where it is known that the patient wished to donate, there is a good chance that this will be possible, and any suffering and risk associated with ventilation is manageable and not disproportionate.

Whether the risk is reasonable is a challenging question to answer. The practical reality is that if ventilation is avoided, the vast majority of these patients will die in a way that donation becomes impossible before donation can be discussed with the SDM. On the other hand, if ventilation is initiated and the SDM clarifies that donation and continued ventilation are not in the best interest of the patient, ventilatory support can be withdrawn and end-of-life care can be initiated. Initiation of ventilation, however, does introduce a possible risk that ventilation interrupts the dying process and creates a situation where the patient does not die quickly after withdrawal of measures, but instead progresses to a persistent vegetative state.

As a practical matter, this tension between an advance directive refusing life-sustaining measures and registration as an organ donor is unlikely to arise often because the majority of patients with explicit advance directives have significant co-morbidities that would limit their eligibility to donate organs. However, rare cases may still arise, and it would be wise to educate the public and those involved in helping people to complete advance directives about this potential tension so that their dominant wish can be clearly expressed in their advance directive.

6. Conclusions

The administration of PMIs to preserve the opportunity to donate, to assess the eligibility to donate, or to optimize the outcomes of donation and transplantation are controversial because they involve the administration of nontherapeutic interventions to a living patient in order to secure medical benefits for third parties.

The legal problems with PMIs in such cases have to do with when surrogate consent is required for PMIs, and whether consent may legally be given for a particular PMI. In some locations, legislators have chosen to enact specific laws to address this problem, with some jurisdictions choosing to enumerate PMIs that are permitted and others choosing to specify those that are prohibited (implying that those not mentioned are permitted). Where a specific law is not enacted, the same problems will need to be resolved according to generic medical consent rules.

This review has shown that specific legal attention to PMIs within organ donation and transplantation legislation has considerable advantages in terms of clarity and public transparency, although these laws do not and probably cannot resolve all uncertainties. There is an inescapable judgment call at the heart of the problem between ensuring that incapable patients are not instrumentalized and harmed by the administration of PMIs while also recognizing that they have interests in altruistic donation and so may be harmed by default exclusion from participation in the social institution of organ donation and transplantation. Too broad an interpretation of a patient's best interests or imaginative attribution of values and beliefs to the patient would allow SDMs to consent on their behalf to interventions that the patient would have rejected if capable, while too narrow an approach would reduce their access their chances of leaving a successful legacy. Thoughtful categorization of PMIs in relation to the degree of benefit they offer for transplant success and the degree of risk or harm posed to the patient strikes us as essential. This should be done in a public, transparent and enforceable way that will increase uniformity and support public understanding of the donation and transplantation system.

Legal commentators tend to call for explicit clarification of the law to address PMIs, and this is the natural inclination of the legal members of this authorship team. At the same time, professional guidelines may also be useful to resolve some of these uncertainties without having to resort to changing the laws, although those guidelines must comply with existing legal constraints. Should those constraints not be optimal, legal reform will be needed. The route of addressing PMIs in professional guidelines might be a simpler way of proceeding given the generally slow pace of legal reform. Whichever approach is taken must include public outreach in order to maintain public trust and acceptance, particularly among populations whose experiences with the medical system may make them reluctant to participate in organ donation.

Our main recommendation is that all jurisdictions consider these issues and address them in current and future legal reform projects. Unfortunately, some recent reforms have failed to do so. For example, the Manitoba Law Reform Commission released a 103-page Consultation Paper titled "Presumed Consent Organ Donation" in May 2021 without addressing PMIs or how consent to these interventions should work.

Further, to reduce the complex tension between DNR orders, advance directives and donor registration, we recommend better education for the public and for lawyers involved in drafting advance directives, so that they may include wording that clearly states which of their wishes would trump when a

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donation registration and an advance directive are in conflict. For example, this wording could state, "the patient does not want heroic measures, but they do want temporary measures to save their life or stabilize their condition for the purposes of donation."

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