

Non-Therapeutic Intensive Care for Organ Donation

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NON-THERAPEUTIC INTENSIVE CARE FOR ORGAN DONATION

Interventions to improve donation outcomes can be completed both pre- and post-mortem. However, pre-mortem interventions are more ethically challenging precisely because the individual is still alive. The applicable ethical and legal considerations for living patients are different from those for deceased donors. Yet, these rules are intertwined in many donation situations.

WHAT ARE PRE-MORTEM INTERVENTIONS?

Pre-mortem interventions (PMIs) are interventions that are performed on patients, before their death, for the purpose of improving organ transplant outcomes or increasing donation opportunities. PMIs are treatments that are not aimed at medical benefit for the patient who is a donor, but rather to improve the function of organs post-transplant. But PMIs can benefit the donor in non-medical ways, most notably by helping to fulfill their choice to donate organs after death.

PMIs may include taking blood for organ matching, administering medications such as anticoagulants, and performing procedures like the placement of lines into blood vessels to enable more rapid cooling of organs once the patient has died. (1) Interventions may also include the initiation and maintenance of life-sustaining therapies (e.g. mechanical ventilation) with the intent to preserve donation opportunities rather than because those therapies offer much chance of meaningful recovery for the patient.

Various terms are used to describe these different kinds of non-therapeutic interventions, including pre-mortem interventions, ante-mortem interventions, and non-therapeutic intensive care for organ donation. For the purposes of this brief summary, we refer to them as PMIs.

DO PMIS REQUIRE CONSENT?

The laws vary from jurisdiction to jurisdiction, but as a general proposition, consent is usually required for PMIs. Consent to donate does not amount to consent to all PMIs. Informed consent is almost invariably required for medical interventions upon a living patient. Signing a donation card or registering a willingness to donate does not constitute informed consent for the use of all pre-mortem interventions, given that patients are very unlikely to have contemplated most of these types of PMIs. (2) The more invasive or intrusive the PMI, the more detailed the consenting process should be.

There is perhaps a grey zone surrounding what might be widely understood as included in the donation procedure and, therefore, may not need explicit consent. For example, the need for bedside imaging or blood tests to safely and suitably match organs to a transplant recipient could be considered an inherent part of the donation process, thus not requiring separate, explicit consent. However, if the proposed PMI carries risk beyond what is experienced in routine intensive care (e.g., surgical biopsies) or alters end-of-life care (e.g. withdrawal of life sustaining measures in or near the operating room), then more detailed consent is needed.

Ideally, first-person consent would be obtained, but this is almost never possible for deceased donation because patients are usually severely injured and incapable. Thus, PMI consent, or assent in some jurisdictions, will almost always be obtained from substitute decision makers (SDM). Notably in Ontario, a substitute decision maker is defined as a person who is authorized to give or refuse consent to a treatment on behalf of a person who is incapable with respect to the treatment. (3) Substitute decision makers should follow the wishes of the patient, or when those are unknown, do what is in the patient's best interests as they understand them. (4)

PMIS IN NOVA SCOTIA AND SCOTLAND

In 2021, Nova Scotia passed the Human Organ and Tissue Donation Act which explicitly addresses the use of PMIs, making it the first province in Canada to have PMIs directly mentioned in its donation law. The law states that consent to donate organs does not automatically imply consent for the use of PMIs. But an individual with the capacity to give voluntary and informed consent may consent to the use of PMIs, and an SDM may do so for an incapable individual. (5) Consent to PMIs given under the Act gives full authority for a physician or hospital to perform such interventions when consent is given, or, where it is contained in a personal directive made pursuant to the Personal Directives Act or other lawful advance directive, when the personal directive or advance directive is activated. (6)

Taking a different approach, the Human Tissue (Authorisation) (Scotland) Act 2019, gives legal support for clinicians to perform PMIs by codifying a list of acceptable 'pre-death procedures' divided between Type A (routine and less-invasive procedures, which did not need further authorisation from the nearest relative) and Type B (rare and more-invasive procedures, which required further authorisation). The Scottish legislation enshrines in law the additional requirement of a "duty to inquire" of the nearest relative and others who may be able to provide evidence regarding the potential donor's most recent views in relation to organ donation and the carrying out of pre-death procedures. A national campaign in Scotland, linked to the introduction of Deemed Authorisation, provided a leaflet to every household explaining PMIs (pre-death procedures).

ETHICAL ISSUES SURROUNDING PMIS

PMIs can be ethically controversial, as they are performed on patients before the determination of death in order to preserve or enhance the possibility of organ donation.

In a recent review of the ethical issues surrounding PMIs, the most frequently cited concerns related to the legitimacy of consent and possible harms to the patient-donor. (7)

Consent for PMIs relies on an understanding of benefit to the patient who is a potential donor that goes beyond medical benefit. This would include benefits such as post-mortem legacy or desire to perform an altruistic act even after death. These interests are widely recognized in society in the form of wills and testaments that govern the transfer of economic assets after death. If these interests are recognized in the setting of deceased donation, they justify SDMs consenting to reasonable potential risks from PMIs if they believe that the patient who is a potential donor would place a value on the altruistic act of organ donation. Many jurisdictions explicitly allow consideration of non-medically therapeutic benefits when consenting for medical treatments including PMIs. (8) Thus, the central ethical challenge raised by PMIs relates to the moral obligations of benevolence and the obligation not to inflict harm on the living patient who is a potential donor. Non-medical benefits such as respecting the desire to donate or honoring a legacy of altruism likely justify the acceptance of a proportionate degree of risk. (9)

The potential harms consisted of two principal types: physical harms and non-physical harms such as harms to interests like dignity and autonomy: (10)

- **PHYSICAL HARM:** A concern with the use of PMIs is that they might cause physical harm to the donor. Harm can be minor, such as discomfort from a blood draw or placement of an arterial line for accurate death determination. Physical harm may be more serious if there is brain hemorrhage after administration of heparin or if measures such as ventilation for donation interrupts the dying process and the patient progresses to a persistent vegetative state. (11) It can be unclear which physical harms are considered trivial and acceptable and which harms are unacceptable. These issues must be discussed both in policies related to PMIs and on a case-by-case basis when novel PMIs are proposed or patient characteristics cause potential for increased risk.
- **NON-PHYSICAL HARM:** A common argument against the use of PMIs is that they treat the patient who is a potential donor as an instrument for the good of the potential organ recipient. There are also concerns related to bodily integrity, the potential disruption of the family's ability to be with the patient, or the violation of an unexpressed desire not to become an organ donor. Similarly, the medicalization and prolongation of the dying process might reduce the patient's experience of a private and dignified death. This may be particularly offensive when the patient specifically instructed that they did not want invasive interventions such as mechanical ventilation or CPR. However, if the patient truly desires donation, not performing PMIs that allow donation could also do harm. The UK Donation Ethics Committee identified the non-physical harm that may be caused by doing wrong to the patient by ignoring their expressed wishes to donate as part of their end-of-life care. (12)

Other ethical concerns with the use of PMIs relate to resource allocation and donation within the broader society:

- **RESOURCE ALLOCATION:** A concern with the use of PMIs relates to the scarcity of ICU resources and the potential conflict for access to those beds. The use of ICU resources for donation could cause harm if it denied access to a patient who could be saved with ICU care, even if donation also potentially saves the lives of transplant recipients. Conflicts of this type could cause moral distress to medical providers.¹³ This is balanced by other work which identifies the net societal positive health impact which comes from facilitating donation. (14)
- **SOCIETAL HARM:** A possible societal harm could be the loss of trust in the donation and transplant system where some may be concerned that all efforts are not being taken to preserve the life of a patient or that people are instrumentalized.

PRACTICAL CONSIDERATIONS FOR PMIS

- Clear communication from physicians to the patient and/or their family regarding organ donation and PMIs is essential. Patients or substitute decision makers should be fully informed of the risks and benefits of any PMI.
- Build and enhance trust in our organ donation systems and institutions around the world.
- The risk associated with the PMI must be proportionate to the potential benefit unless specifically authorized by the patient with informed consent.
- Newly proposed interventions should be reviewed carefully for medical efficacy and potential ethical risks.

LOOKING AHEAD: OPPORTUNITIES TO INCREASE THE USE OF, AND SUPPORT FOR, PMIS IN ORGAN DONATION

- Organ donation organizations should investigate the option for obtaining first person consent regarding the use of PMIs (e.g., when prospective donors are competent and conscious).
 - Jurisdictions updating their donation and transplant legislation should consider explicitly addressing PMI consent, using examples such as Scotland and Nova Scotia to create consent models that clarify the legal standing of consent for PMIs.
 - Public awareness campaigns: Education should be offered to the public to build a basic understanding of PMIs. An example would be Scotland, which has recently included public education around PMIs as part of their public outreach. Provide general information on PMIs, with some of the associated benefits for transplant outcomes and potential risks to the donor. Engage with the public about donation and PMIs.
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- Update the organ donation registration process: Communicate more information on PMIs when individuals register to become a donor. Organizations should strive to provide the public with accurate information on PMIs when they register to maintain public trust in the organ donation system.
- Update donation program websites to include information on PMIs
 - For example, see “Medical tests and Procedures,” Scotland Organ Donation. <https://www.organdonationscotland.org/medical-procedures-and-tests>

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- (3.) Health Care Consent Act, SO 1996, c.2, sched A at s9. [HCCA].
- (4.) See note 3 at s 21(1).
- (5.) The Human Organ and Tissue Donation Act, NS, 2021, c6 at s22(1)(2).
- (6.) See note 5 at s 22(5)(a) and (b).
- (7.) Weiss, M.J. et al. (2021). Ethical considerations in the use of pre-mortem interventions to support deceased organ donation: A scoping review. *Transplantation Reviews*, 35(4), 100635.
- (8.) For example, courts in the UK have held that best interests do not cease at the moment of death. We have an interest in being remembered as having done the "right thing", either in life or, postmortem. See: *Re M* [2009] EWHC 2525 (Fam) (particularly at para 38).
- (9.) Weiss, M.J. et al, see note 7.
- (10.) Weiss, M.J. et al, see note 7.
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