
ORGAN AND TISSUE DONATION AND TRANSPLANTATION

See also [CMA Policy on Organ and tissue donation and transplantation](#)

Context

Organ donation wait lists in Canada continue to grow exponentially due to an aging population, climbing obesity rates, the increasing viability of organ transplantation, and improvements in the effectiveness of immunosuppressive medications.^{1, 2} It is projected that demand for organ transplants will increase 150% over the next two decades.³

Presently, nearly 4500 Canadians remain on organ transplant waitlists, some of whom will die before receiving a donation; 260 patients died while waiting for an organ transplant in 2016.⁴ The majority of organ donations are made by deceased donors (81% in 2015)⁵ and the majority of Canadians (91%) support organ and tissue donation, however, only 51% have registered their consent.⁴

In 2016, 2903 organ transplantations were performed in Canada using donations made by 758 deceased donors (548 NDD^a donors and 174 DCD^b donors) and 544 living donors. The rate of deceased organ donation in 2016 (20.9 donors per million people [DPMP]) represents a 42% increase compared to 2007 (14.7 DPMP). However, this value still falls short of the 2017 goal set out in Canada's strategic plan to improve organ and tissue donation and transplantation (22 DPMP), and also falls short of the performance of similar nations (e.g., the United States, 30.98 DPMP).³

Compared to deceased donation, living donation offers better short-term and long-term health outcomes for recipients.⁴ Living donors can bequeath a kidney, a lobe of lung or liver, bone marrow, umbilical cord blood, and/or stem cells through a directed (i.e., the organ is intended for a specific patient designated by the donor) or non-directed donation. Due to advancements in immunosuppressive technology, donors may be related or unrelated to the recipient⁶, and are matched based on appropriate compatibility tests. The rate of living donation (15.03 DPMP in 2017) has decreased by 11% since 2006. Interestingly, certain services do not follow this trend; for example, the Kidney Paired Donation program, established in 2009, had its second most successful year in 2016 and has a total of 474 transplants facilitated to date.

^a Neurological Determination of Death (NDD): determining death based on neurologic or brain-based criteria.

^b Donation after Cardiocirculatory Determination of Death (DCD): determining death based on permanent cardiocirculatory failure.

Oversight

In 2007, the Canadian Council on Donation and Transplantation merged its duties with Canadian Blood Services⁷ to facilitate integrated national coordination of the OTDT system (except Quebec). Canadian Blood Services is now responsible for developing standards and clinical practice guidelines, improving donation and transplant services, increasing information transfer, and monitoring Canada's performance compared to other developed nations.⁸ Organ donation organizations (ODOs) continue to oversee the planning, promotion, coordination, and support of OTDT at the provincial level, within a nationally agreed upon strategy directed by Canadian Blood Services. Since 2007, national initiatives such as the Kidney Paired Donation (KPD) program, the Living Donor Paired Exchange (LDPE), and the Highly Sensitized Patient (HSP) kidney sharing program have emerged in an effort to centralize the coordination and practice of OTDT. While improvements in national coordination have been made, use of the Canadian Transplant Registry and the National Organ Waitlist varies among ODOs⁴, making it difficult to evaluate and enhance system performance.

Legal Foundations of Organ and Tissue Transplantation

Federal regulations and provincial legislations govern the practice of OTDT in Canada. Health Canada has standardized the screening, testing, and handling of donated organs and minimally manipulated cells and tissues under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*⁹, with the purpose of minimizing potential health risks to Canadians receiving transplantation. Provincial and territorial legislation provide a framework for facilities and personnel undertaking organ and tissue donation and transplantation activities, including procedures for the independent determination of death.¹⁰

Legal definition and determination of death

Provincial and territorial law (with the exception of Nunavut)¹¹ prescribe the process of determining death for the purposes of post-mortem organ transplantation.¹²⁻²³ However, while these provisions specify the requisite qualifications and number of physicians required to determine death, they defer the technical diagnosis of death to accepted medical practice rather than offering a legal definition. At present, only Manitoba,¹⁵ Prince Edward Island¹⁷ and the Northwest Territories²³ have an established statutory definition of death. A more recent Nova Scotia bill on organ and tissue donation, which was passed in 2010, also provides a statutory definition of death.²⁴ Greater clarity around definitions of death would better support clinical decisions on the medical determination of death.

Contemporary Ethical Challenges

1. Medical determination of death

The majority of organ donations are provided by deceased donors.⁵ The ethical standard for organ donation is known as the *Dead Donor Rule* (DDR), which specifies that organs may only be procured for donation *after* a declaration of death (i.e., organ donation cannot cause death).²⁵ Traditionally, the DDR, together with strict definitions of death, has provided the foundation for ethical organ donation since the practice began. However, advances in life-sustaining treatment²⁶, evolving understandings of patient autonomy, and different understandings of what constitutes death (e.g., brain death vs. cardiocirculatory death)²⁷, have blurred the line between life and death. This contemporary situation has introduced ethical dilemmas for medical professionals performing organ and tissue transplantation.

Donation after neurological determination of death (NDD)

Neurological determination of death (NDD) describes the permanent cessation of functioning in the brain, cortex, and brain stem (“whole brain death”). This is a clinical determination that must be made in absence of confounding factors by a licensed physician with the skills and knowledge to interpret test results.²⁸ Donation after NDD is sometimes controversial, especially for those that view cardiocirculatory death as the only acceptable determination of death (e.g., some religious groups) and in view of life-sustaining technology that keep the heart beating when it would otherwise fail.

Donation after cardiocirculatory determination of death (DCD)

DCD may be *uncontrolled* or *controlled*. Uncontrolled DCD refers to circumstances where donation is initially considered *after death has occurred but was not anticipated*.

Controlled DCD on the other hand, refers to circumstances where donation may initially be considered when *death is anticipated, but has not yet occurred*, posing a potential ethical dilemma. Controlled DCD involves patients who suffer from a catastrophic brain injury or other terminal condition who are removed from life-sustaining measures (e.g., a mechanical ventilator) with the recognition that they have no chance of recovery.²⁹

Some contend that controlled DCD may contravene the DDR since continued cardiac and neurologic functions are contingent on the consensual decision not to provide resuscitation and/or to withdraw supportive technologies. This raises the concern that “irreversible” is used equivocally in the neurological and the cardiocirculatory definitions of death. Professional societies have widely accepted the permanence standard for death determination in DCD, which infers that interventions to restart circulation will not be applied and spontaneous resumption of circulation is no longer possible.

DCD has become an accepted practice in many countries around the world. In Canada, provinces are increasingly implementing capacity to allow for DCD^c. Recent upward trends in organ and tissue donation in Canada are largely attributable to this shift towards DCD (DCD; 4.8 DPMP in 2016).⁴ For example, organ donation increased 57%

^c As of 2016, DCD was practiced in 5 of 11 provincial organ donation organizations, with two others beginning implementation (reference: https://professionaleducation.blood.ca/sites/ansi/files/odt_report-2017-final.pdf)

in Ontario during 2016, with DCD accounting for 23% of the total donations made by deceased donors.⁴

Canada introduced ethical and clinical practice guidelines in 2005 that clarified the practice of DCD³⁰; however, ethical questions such as those surrounding “potential harm” remain. For example, the ante-mortem (pre-death) administration of anti-coagulant medications can improve the likelihood of successful transplantation³¹ but offer no benefit to the potential organ donor.³² At this time, legislation does not address the issue of consent for ante-mortem interventions that significantly improve the rate of organ viability but provide no medical benefit to the dying potential donor. However, the practice is supported by the aforementioned national guidelines endorsed by the Canadian donation and transplantation community.

Identification and referral of potential donors

Potential donor identification and referral, while legislated in many jurisdictions, is an important area of continued development as failure to identify donors deprives families the opportunity to donate and deprives patients of potential transplants. In order for any Canadian who may wish to donate their tissues and/or organs is given every reasonable opportunity to do so, the outreach of ODOs and physicians specializing in donation is an important consideration. While identification/referral is not intended to interfere with end of life discussions it can be perceived in this way. Methods to normalize this process within end of life discussions is an area of ongoing discussion and research.

Religious and cultural understandings of death and donation

As the composition of Canadian society continues to change, cultural awareness will become a key competency for health care professionals, especially those working in the arena of OTDT. Religious and cultural traditions often become important during times of illness, death, and dying³³, and have implications for the withdrawal of life sustaining therapies and the donation of organs and tissue. Generally, the religions most predominantly practiced in Canada^d are supportive of organ and tissue donation³⁴, though it is important to note that individual and familial religious views and cultural practices can vary widely.

2. Consent

Informed consent for living donation

Some argue that organ donations by living donors undermine the foundational principle of medical ethics, *non-maleficence*, by exposing healthy individuals to potential physical, psychological, and other harms. Others support the view that living donation is ethically acceptable when free and informed consent is given by a competent, medically and psychologically suitable adult. Provincial and territorial laws also mandate a requirement for consent before a living donation.^{11-20, 22, 23} In the absence of a federal standard as guidance, transplantation centres are left to develop their own standards of informed consent and, as such, practice varies across jurisdictions.

^d The most practiced religions in Canada are Christianity (67.3%), Islam (3.2%), Hinduism (1.5%), Sikhism (1.4%), Buddhism (1.1%), and Judaism (1%) – 23.9% do not affiliate with a specific religion (Statistics Canada, 2011)

Informed consent is an important ethical and legal^e mechanism that respects patient autonomy and contributes to patient safety in the context of living organ donation.

Informed consent is given when:

(1) the patient, or substitute decision-maker, is assessed to be competent, (2) the patient is provided with adequate information on which to base their decision (e.g., the risks associated with the procedure for both donor and recipient; potential outcomes and alternative treatments available to the recipient; the risk of rejection), (3) the patient understands the information they have been given, and (4) the decision is made free of coercion or pressure (i.e., voluntary).³⁵

Informed consent for deceased donation

Respect for a patient's dignity and autonomy is a pillar of modern medicine, and their consent to OTDT is legally binding in almost all jurisdictions.^f In practice, however, provincial and territorial donation agencies routinely allow families to veto the legally valid consent to donate organs and/or tissue provided by a deceased loved one.³⁶ For example, in Ontario in 2015, 21% of families of registered organ donors refused donation.³⁶ Agencies' reluctance to honour what is considered legally binding consent by law in the absence of further consent by next of kin or a substitute decision-maker stems from a lack of awareness about provisions in the law, concern for the welfare of families, and concerns over public perception of organ donation programs.³⁷ There is also evidence to suggest that some members of organ donation organizations are misinformed about the rules on consent that make up the legal framework supporting the practice of OTDT in Canada.³⁸

Patients undergoing medical assistance in dying (MAiD) may also be eligible for organ and tissue donation, contingent on consent and other applicable factors – see relevant policy guidelines.⁵

3. Organ availability and equitable distribution

Due to a disparity between the need and availability of organs, OTDT is an arena which challenges the ideals of universality and accessibility set out in the *Canada Health Act*. OTDT allocation policies attempt to strike a balance between justice, equal opportunity, and utility although, in this context, these principles are often in conflict.

The current provincial variation in transplant activity and wait times raise concerns of significant inequity in access to organ transplantation in Canada. Waitlist referral and organ-allocation criteria are, for the most part, neither public nor standardized. Allocation

^e Most provinces and territories have healthcare legislation that define the elements of consent in the medical context, although these must be read in conjunction with P/T organ and tissue donation legislation. See for instance Ontario's *Health Care Consent Act*, SO 1996, c 2, sched A. The courts have also issued a body of decisions on consent to treatment. According to the Supreme Court of Canada, disclosure must be viewed from the patient's lens and must include "material information" - i.e., information that a reasonable person in the patient's position would want to know (see *Reibl v Hughes* [1980] 2 SCR 880). Caulfield also provides a summary of the law of consent for living organ donation [here](#).

^f Toews & Caulfield (2016) provide a comprehensive chart outlining provisions that indicate the legally binding nature of consent to organ and tissue donation after death and where family veto is legally permitted. The situation is more blurred in three jurisdictions: the Northwest Territories, Quebec, and Manitoba.

criteria vary among provinces, inhibiting the systematic sharing of organs across jurisdictions in what is meant to be a national organ and tissue allocation system that triages cases based on urgent need and longest wait time.⁴ Such geographic inequity exists that in some provinces patients are more than twice as likely to receive an organ compared to those living elsewhere.³ Similarly, Aboriginal persons, despite being twice as likely to suffer from end-stage liver disease compared to the rest of the Canadian population, wait significantly longer and are less likely to receive a transplant.³⁹

Public appeals for living donors

Some members of the Canadian OTDT community (e.g., The Kidney Foundation of Canada, the Canadian Society of Transplantation) explicitly support public solicitation of anonymous, willing, living donors.⁴⁰ As long as the donor or a third party does not receive material gain (i.e., transplant commercialism), the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation⁴¹ and the Canadian Society for Transplantation⁴² allow for public appeals to encourage altruistic donation. Despite this, concerns remain regarding the fairness of making such appeals. For instance, those with larger social networks, who hold prominent professional positions or celebrity status, may have an increased chance of successfully finding a suitable donor through public solicitation. Furthermore, public appeals bypass the systemic infrastructure that others must navigate, resulting in the death of some whose condition collapses before receiving an organ.

4. Increasing organ availability and donation rates

Presumed consent (opt-out policies)

Currently, most Canadian jurisdictions operate under an opt-in system for OTDT, whereby the default assumption is that patients do not wish to donate their organs after their death unless they expressly consent to doing so; Nova Scotia stands as a recent example of a province moving to an opt-out system, whereby consent to donate organs and/or tissue is presumed in the absence of an explicit directive stating otherwise. While the majority of the Canadians are in favour of donation, only a fraction of those supportive individuals are registered as donors⁴³, providing a basis for this discussion. However, recent public opinion data shows Canadians are divided over whether presumed consent laws should be enacted.⁴ Basic considerations for each system follow.

In an opt-in system:

- The intent of a potential donor, which is of primary concern, is not often clear if their wishes were not registered. Physicians must often engage family members and loved-ones in a discussion regarding donation without any clarity of the potential donor's intent.
- The lack of a clear intention and the need to broach a difficult discussion with family/loved-ones at a time of crisis adds to the complication of getting a healthy organ to a matched patient, often in dire need of transplant, in a timely manner.
- Registration of intent safeguards against the possibility of an unintended donation taking place.

In an opt-out system:

- The conversation between physicians and family/love-ones is normalized. Importantly, input from these persons should still be considered strongly when no specific intent was registered by the deceased person.

- Testing for donation can be integrated more broadly into hospital services – increased capacity would be required in several areas including donor identification, national logistics, and counselling services.
- The ability of an individual to opt-out, either fully or partially, must be universal in both awareness and access to safeguard against the possibility of an unintended donation taking place. This has important educational and infrastructure implications.

Further discussion is required for issues such as those surrounding awareness, education, and healthcare system/jurisdictional access to pre-registered information in the event of sudden incapacitation or death. On this latter point, and for example, accurate means of tracking opt-out status across regions or jurisdictions (such as an electronic health record accessible in any hospital) is necessary so as to avoid falsely presuming consent outside the reach of the tracking system. Regarding education, the need to provide the public with pertinent facts about a new system, as well as their options therein, should not be understated.

Evidence suggests that presumed consent alone may not be sufficient to radically increase donation rates. However, in countries where an opt-out system was implemented in conjunction with other measures the rate of post-mortem donation was significantly improved (e.g., Spain, 43.40 DPMP).⁴⁴ These measures include improved infrastructure, complementary legislation, increased funding, and more staff working to identify and build relationships with potential donors.

Elective nontherapeutic ventilation

Elective nontherapeutic ventilation (ENV) is another potential ante-mortem intervention that can improve the quality of organs for donation in patients with catastrophic brain injury whose resulting death is imminent. ENV is ventilation administered with the sole purpose of securing organs for transplant.⁴⁵ Canadians are reluctant to adopt ENV while other, less controversial, means of increasing donation rates have not been employed to their full potential.⁴⁶ While neither the Canadian public nor its donation and transplantation community is ready to consider elective nontherapeutic ventilation, it is practiced elsewhere in the world (e.g., USA, Europe), supported by ethical studies⁴⁷, and accepted by health professionals.⁴⁸ As the national coordination of Canada's donation and transplantation system continues to improve, ENV may be considered in an effort to increase the number of quality organs available to the thousands of individuals on waitlists.

Xenotransplantation

Xenotransplantation, the transfer of living cells, tissues, and/or organs from non-human animal species into humans, has emerged in response to the global shortage of tissue and organs for transplant.⁴⁹ Although xenotransplantation has potentially significant upside, it is currently not an accepted or lawful medical practice due to the associated risk of potential cross-species infection, and an increased risk of recipient rejection. As science and technology evolve, it is possible that xenotransplantation will be a viable alternative or supplement to human organ transplantation.⁵⁰

Organ trafficking and transplant tourism

Canada has taken a firm stance against organ trafficking and transplant tourism, and has participated in and endorsed the Declaration of Istanbul.⁵¹ The CMA unconditionally

endorses the Declaration of Istanbul. Organ trafficking is specifically prohibited under the *Criminal Code*.⁵² As such, it is illegal to buy or sell human organs in Canada. However, thousands of individuals desperate for a transplant participate in transplant tourism overseas each year, including Canadians.^{53, 54} There is significant evidence of state-sponsored forced organ harvesting and organ trafficking in certain countries. This has been well documented in China. Such practices exploit vulnerable populations, commodify the human body, and endanger the lives of donors and recipients.

Conclusion

The rapid development of medical technology, evolution of disease, changing societal expectations and system level changes in OTDT coordination, have resulted in a fast-changing Canadian landscape that can be difficult to navigate for physicians and patients alike. Readers wishing to learn more are encouraged to refer to the literature provided by members of the OTDT community, such as Canadian Blood Services, provincial transplant coordinating bodies (e.g., Trillium Gift of Life Network), and the Canadian Transplant Society.

Glossary

Dead Donor Rule

Vital organs can only be recovered from a deceased person, and that organ recovery must not be the cause of death. In Canada, death is determined based on permanent cardiocirculatory arrest and/or neurological death, guided by clinical and ethical best practice guidelines.³⁰

Cardiocirculatory Determination of Death (DCD)

The standardized process and procedure of medically determining death based on cardiocirculatory criteria. Cardiocirculatory death is defined by the continuous absence of palpable pulse, blood pressure, and respiration, in accordance with leading clinical guidelines.³⁰

Neurological Determination of Death (NDD)

The standardized process and procedure of medically determining death based on neurologic criteria. Brain death is defined as complete and permanent cessation of brain function, with a loss of capacity for consciousness and absence of brain stem reflexes (such as the capacity to breathe), in the presence of clear etiology and absence of other or confounding or reversible conditions.²⁸

Living Donor

An individual in good health who donates to either a related or unrelated recipient.⁵⁵ Living donors may be actually or emotionally related to the recipient. In other cases, donors are strangers and therefore anonymized, such as with Living Donor Paired Exchange (LDPE) programs.

Organ

Whole or parts of a human organ. Transplantation is intended to return said organ to its original specific function following revascularization and reperfusion. This includes any adjunct vessels that are retrieved with the organ for use in transplantation.⁸ Organs are needed for life-saving treatment, can be recovered in a limited number of situations, and must be transplanted immediately.

Tissue

A functional group of human cells. Tissue products generally support life-enhancing procedures, can be recovered from a broader range of donors, and stored for extended periods of time.

Organ Trafficking

The recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat, use of force, or other forms of coercion (e.g., abduction, fraud, deception, the abuse of power or abuse of a position of vulnerability, or

the giving to, or the receiving by, a third party of payments or benefits) to achieve control over the potential donor for the purpose of exploitation by the removal of organs for transplantation.⁵¹

Transplant Commercialism

A policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.⁵¹

Transplant Tourism

Travel for transplantation involving organ trafficking and/or transplant commercialism. Tourism is sometimes promoted through supply of resources devoted to providing transplants to non-resident patients, undermining a country's ability to provide transplant services for its own population.⁵¹

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