BACKGROUND TO CMA POLICY – DRAFT

ORGAN AND TISSUE DONATION AND TRANSPLANTATION (OTDT)

CONTEXT

Organ donation wait lists in Canada continue to grow exponentially due to an ageing 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 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),\(^3\) and falls short of the performance of similar nations (e.g., the United States, 30.98 DPMP).

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 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 recipient,\(^5\) 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 such as the Kidney Paired Donation program, established in 2009, buck this trend, having had its second most successful year in 2016 and with a total of 474 transplants facilitated to date.

Oversight

In 2007, the Canadian Council on Donation and Transplantation merged its duties with Canadian Blood Services\(^4\) to facilitate integrated national coordination of the OTDT system (except Quebec). The CBS is now responsible for developing standards and clinical practice guidelines, improving

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\(^a\) Neurological Determination of Death (NDD): determining death based on neurologic or brain-based criteria.
\(^b\) Donation after Circulatory Death (DCD): Organs are procured after the pronouncement of irreversible cessation of circulatory and respiratory function (i.e., cardiac death).
transplant services, increasing information transfer, and monitoring Canada’s performance compared to other developed nations. Organ procurement organizations (OPOs) continue to oversee the planning, promotion, coordination, and support of OTDT at the provincial level, within a nationally agreed upon strategy directed by CBS. 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 OPO’s, 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, 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.

Legal definition and determination of death

Provincial and territorial law (with the exception of Nunavut) prescribe the process of determining death for the purposes of post-mortem organ transplantation. However, while these provisions specify the requisite qualifications and number of physicians who shall determine death, they defer the technical diagnosis of death to accepted medical practice rather than offering a legal definition. At present, only Manitoba, Prince Edward Island and the Northwest Territories 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 though this law has not received royal proclamation eight years later. 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. 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 procurement cannot cause death). 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 treatment and evolving understandings of patient autonomy, different understandings of what constitutes death (e.g., brain death vs. cardiac death), have blurred the line between life and death, introducing new ethical dilemmas for medical professionals performing organ and tissue transplantation. Discussion
surrounding the diagnosis of death is a contemporary phenomenon, brought on by the advent of life-sustaining medical technology that makes possible the artificial support of cardiac and respiratory function. Neurological determination of death (NDD) describes the irreversible cessation of functioning in the brain, cortex, and brain stem (“whole brain death”). This is a determination that must be made in absence of confounding factors.

**Donation after circulatory death (DCD): Non-heart beating donors**

Donation after circulatory death (DCD) involves patients who suffer from a catastrophic brain injury or other terminal condition who do not meet the criteria for brain death but who are removed from life-sustaining therapy with the recognition that they have no chance of recovery.

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. Some contend that 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 circulatory definitions of death.

In response to organ shortages and medical advances in organ preservation, DCD has become an accepted practice in many countries around the world. In Canada, provinces are increasingly implementing capacity to allow for DCD. Recent upward trends in organ and tissue donation in Canada are largely attributable to this shift towards DCD (DCD; 4.8 DPMP in 2016). For example, organ donation increased 57% in Ontario during 2016, with DCD accounting for 23% of the total donations made by deceased donors.

Canada introduced ethical and clinical practice guidelines in 2005 that clarified the practice of DCD, however ethical questions, such as surrounding “potential harm”, remain. The ante-mortem administration of anti-coagulant medications (e.g., inotropes, vasopressors) can improve the likelihood of successful transplantation, however, they offer no benefit to the dying potential organ donor, and can result in hemorrhaging if a patient reacts adversely. Similarly, ante-mortem administration of heparin (an anticoagulant) decreases the risk of thrombosis following circulatory cessation. At this time, legislation does not address the issue of consent for pre-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.

**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 or regain importance during times of illness, death, and dying.

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and have implications for the withdrawal of life sustaining therapies, and organ and tissue donation. Generally, the religions most predominantly practiced in Canada\(^d\) are supportive of organ and tissue donation,\(^37\) 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\(^38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49\) although in Quebec the Civil Code simply provides that “the wishes of the deceased person be followed, unless there is a compelling reason not to do so”.\(^50\) In the absence of a federal standard as guidance, transplantation centers are left to develop their own standards of informed consent and, as such, practice varies across jurisdictions.

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).\(^51\)

**Informed consent for deceased donation: “Family veto”**

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

\(^d\) 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)

\(^e\) 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: in the Northwest Territories, where the relevant legislation contains provisions stating that a family member who is able to consent to organ and tissue donation can also object to the consent (Human Tissue Act, SNWT 2014, c 30, s 5(4)(d)); in Quebec, the Civil Code provides that “the
donation agencies routinely allow families to veto the legally valid consent to donate organs and/or tissue provided by a deceased loved one. For example, in Ontario in 2015, 21% of families of registered organ donors refused donation. 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 procurement programs. There is also evidence to suggest that some members of organ procurement agencies are misinformed about the rules on consent that make up the legal framework supporting the practice of OTDT in Canada.

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 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. Such geographic inequity exists that in some provinces, patients are more than twice as likely to receive an organ compared to those living elsewhere. 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.

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. 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 Transplantation and the Canadian Society for Transplantation also allow for public appeals to encourage altruistic donation. Despite this support from some stakeholders, 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

wishes expressed shall be followed unless there is a compelling reason not to do so” (Civil Code of Quebec, SQ, 1991, c 64, s 43); in Manitoba, consent by the individual is full authority but the consent is not binding (The Human Tissue Gift Act, CCSM, c H180, 2(3)).
Presumed consent (opt-out policies)

Currently, all Canadian jurisdictions use an “opt-in” system of organ and tissue donation, whereby the default assumption is that patients do not wish to donate their organs unless they expressly consent to doing so, in accordance with the relevant provincial or territorial legislation. In some other countries, an “opt-out” system is used, whereby consent to donate organs and/or tissue is presumed in the absence of an explicit directive stating otherwise. 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). These measures include improved infrastructure, complementary legislation, increased funding, and more staff working to identify and build relationships with potential donors. Recent public opinion data shows Canadian opinion is divided over whether presumed consent laws should be enacted in Canada.

Elective nontherapeutic ventilation

Elective nontherapeutic ventilation (ENV) is another potential pre-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. Canadians are reluctant to adopt ENV while other less controversial means of increasing donation rates have not been employed to their full potential. 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 studies, and accepted by health professionals. 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. 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 (i.e., xenosis), and recipient rejection is much more likely. As science and technology evolve, it is possible that xenotransplantation will be a viable and accepted alternative or supplement to human organ transplantation.
5. 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. Organ trafficking is specifically prohibited under the Criminal Code. 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. 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.

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9 Travel for transplantation involving organ trafficking and/or transplant commercialism.
GLOSSARY

**Dead Donor Rule**
The majority of organ donations are made by deceased donors (81% in 2015).\(^7\) The ethical standard for organ donation and transplantation is whole brain death, however, donation following circulatory death is also practiced in Canada, guided by ethical and best practice guidelines.

**Donation after Circulatory Death (DCD)**
The option to donate organs and/or tissue following the decision to withdraw life-sustaining treatment (e.g., a mechanical ventilator) even though a patient does not meet the criteria for neurological death. Organs are procured after the pronouncement of irreversible cessation of circulatory and respiratory function (i.e., cardiac death).

**Living Donor**
An individual in good health who donates to either a related or unrelated recipient.\(^7\) 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.

**Neurological Determination of Death (NDD)**
The standardized process and procedure of determining death based on neurologic or brain-based criteria. Brain death occurs when the brain has completely and irreversibly ceased to function. In Canada, evidence of whole-brain death (i.e., the death of the entire brain, cortex and brain stem), is necessary for a NDD.\(^3\)

**Organ**
Whole or parts of a perfusable human organ for use in transplantation with the intention of returning 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.\(^7\) Organs are needed for life-saving treatment, can be recovered in a limited number of situations and must be transplanted immediately.

**Organ Trafficking**
The recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deceptions, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation.\(^6\)

**Tissue**
A functional group of human cells for use in transplantation. Tissue products generally support life-enhancing procedures, can be recovered from a broader range of donors and stored for extended periods of time.
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.66

Transplant Tourism
Travel for transplantation involving organ trafficking and/or transplant commercialism, or if the resources (e.g., organs, professionals, transplant centers) devoted to providing transplants to patients from outside a country undermine the country’s ability to provide transplant services for its own population.66
References


8 Safety of Human Cells, Tissues and Organs for Transplantation Regulations SOR/2007-118, s 2; the enabling Act of these regulations is the Food and Drugs Act, RSC 1985, c F-27.


The Human Tissue Gift Act, CCSM, c H180, ss 9, 10. Available: http://canlii.ca/t/5b54 (accessed 2018 Dec 20)


Human Tissue Act, RNWT (Nu) 1988, c H-6, s 1. Available: http://canlii.ca/t/8j0r (accessed 2018 Dec 20)

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