ORGAN AND TISSUE DONATION AND TRANSPLANTATION

RATIONALE

Organ and tissue transplantation represent significant lifesaving and life-enhancing interventions that require careful consideration by multiple stakeholders spanning medical disciplines. Technological and pharmacological advancements (e.g., split organ transplants, ex vivo organ perfusion) have made organ and tissue transplantation increasingly viable as a successful treatment option for related and causal medical conditions. Moreover, changing social norms have led to shifting perceptions of the acceptability of organ and tissue donation. Within this rapidly changing context, there is a need for renewed consideration of the ethical issues and principles guiding organ and tissue donation and transplantation (OTDT) in Canada. This policy identifies foundational principles to address the challenges surrounding deceased and living donation. The overarching principle that guides OTDT is public trust, and policies and mechanisms that guide OTDT in Canada should aim to maintain and foster public trust in the system of organ donation.

The CMA acknowledges and respects the diverse viewpoints, backgrounds, and religious views of physicians and patients and therefore encourages physicians to confront challenges raised by OTDT in a way that is consistent with both standards of medical ethics and patients’ values and beliefs.

SCOPE

In conjunction with applicable laws and regulations in Canada, the Declaration of Istanbul, and the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation, and leading clinical practices, this policy aims to provide guidance to physicians on key ethical considerations pertinent to the practice of OTDT in Canada. Although there are areas of overlap, organ donation and transplantation (ODT) and tissue donation and transplantation (TDT) are characterized by different processes and unique challenges. The following document will focus on ODT because many of the contemporary ethical challenges within this context are specific to organ recovery and donation; however, concepts may also apply to TDT. This policy is intended to address OTDT in adult populations. The challenges, considerations, legislation, and policy surrounding pediatric and neonatal OTDT are unique and deserve focused attention.
Physicians should be aware of relevant legislation, regulatory requirements, and policies in the jurisdiction in which they practice. Physicians are encouraged to refer to the various Canadian specialty societies that deal directly with OTDT for up-to-date information and policy, as well as innovative techniques and approaches.

GUIDING PRINCIPLES

1. JUSTICE

There is a continuous need to improve the efficiency and effectiveness of organ donation and transplantation (ODT) in an effort to narrow the gap between supply and demand, in what remains a scarce resource. ODT should be governed by the principle of justice, particularly according to a view of justice that calls for fairness and transparency in the allocation of organs and tissues.

Allocation criteria should be externally justifiable and appropriately and transparently defined in conjunction with clinical criteria. Considerations of fairness and transparency should continue to guide and influence the equitable allocation of organs and tissue (e.g., prioritizing medical need or by length of time on the wait-list) in a manner that is open to public scrutiny. This is often balanced with medical utility, according to which allocation aims to maximize the greatest good for the greatest number of patients (e.g., prioritizing based on the probability of transplantation success).

There should be no discrimination based on social status or perceived social worth. Lifestyle or behavioral factors should only be considered when there is clear evidence that they will impact the medical probability of success.

The donation or transplantation of organs and tissues should not be hinged on the patient’s ability to pay. Such action is inconsistent with the principles that underlie Canada’s publicly-funded health system and compromises the voluntariness of the donor’s choice (see discussion below).

All Canadians should have the opportunity to become aware of the option of donation and be given the opportunity to choose whether to donate.

In view of their knowledge and expertise regarding the benefits of transplantation and consistent with widespread Canadian support for donation and transplantation, physicians are in a unique position to actively promote consideration of organ and tissue donation. All levels of government should continue to support initiatives to improve the ODT system, raise public awareness through education and outreach campaigns, and fund ongoing research, such that Canadians who may wish to donate their organs are given every reasonable opportunity to do so. Policymakers should continue to explore and appraise the evidence on policy interventions to improve the rates of organ donation in Canada.

While every effort should be made to allocate organ donations after death equitably, the CMA recognizes that living organ donors often volunteer to donate to a loved one or acquaintance (i.e., via
The CMA recognizes the importance of personal commitments and attachments, as such, directed donations are ethically acceptable as long as potential living donors are informed of all options, including the option to donate in a non-directed fashion.

To diminish inequities in the rates of organ donation between jurisdictions, federal and provincial governments should engage in consultations with a view to implementation of a coordinated, national strategy on ODT. Efforts should be made to ensure adequate education and engagement with potential living donors from communities that have historically had lower living donor rates, in order to reduce inequities in access to living donation in Canada.

2. BALANCING BENEFICENCE AND NON-MALEFICENCE

According to the CMA Code of Ethics and Professionalism, balancing beneficence and non-maleficence means to: consider first the well-being of the patient; always act to benefit and promote the good of the patient; provide appropriate care and management across the care continuum; take all reasonable steps to prevent or minimize harm to the patient; disclose to the patient if there is a risk of harm or if harm occurs; recognize the balance of potential benefits and harms associated with any medical act; and act to bring about a positive balance of benefits over harms.

DECEASED DONATION

Prospective donors, while still alive, can benefit from the knowledge that they can potentially save lives after their own deaths. Donation can also provide comfort to the family of the donor by allowing them to fulfill the wishes of their deceased loved one.

However, potential donors must not be harmed by the act of donating. In accordance with the Dead Donor Rule (DDR), organ or tissue procurement should never be the cause of death. Leading clinical criteria in conjunction with legally prescribed definitions of death and procedures, should inform the determination of death before donation procedures are initiated.

Donation after cardiac death (DCD) can be considered in patients who do not fulfill brain death criteria, but who have no hope of recovery. DCD should be practiced in compliance with the regulations of individual transplant centers, leading Canadian clinical guidelines and relevant legislation.

Physicians determining that a potential donor has died should not be directly involved in tissue or organ removal from the donor or subsequent transplantation procedures, nor should they be responsible for the care of any intended recipients of such tissues and organs (from WHO Guiding Principle 2).

Donation After Cardiac Death at End of Life

End-of-life decisions must be guided by an individual's values and beliefs of what it means to have a meaningful life and death. Physicians should make every reasonable effort to be aware and
considerate of the cultural and religious views of their patients as they pertain to ODT. Likewise, institutions should provide continuing professional development opportunities for physicians to develop and apply cultural competence in contexts of ODT.

Moreover, the care of the dying patient must never be compromised by the desire to protect organs for donation or expedite death to allow timely organ retrieval.

LIVING DONATION

Living donors are motivated to act primarily for the benefit of the recipient. The perceived acceptability of living donation varies from person to person; living donation is deemed to be ethically acceptable when the potential benefits outweigh the potential risks of living donation; when living donors provide informed consent, meet medical and psychological requirements and receive appropriate follow-up care. It is not necessary for the potential donor to be biologically or emotionally related to the recipient.

3. INFORMED CONSENT AND VOLUNTARINESS

Donation should always be an autonomous decision, free of undue pressure or coercion. By law, the potential organ donor, or their substitute decision-maker, must always consent to donation. Information provided to members of the public should be clear and complete so that individuals can make an informed decision regarding whether they want to donate organs and tissues. Areas of controversy should be discussed honestly and differences in religious or philosophical beliefs regarding death should be acknowledged.

To protect the voluntariness of the potential donor’s decision, public appeals to encourage altruistic donation should not seek to compensate potential donors through payment and should not subvert established systems of organ allocation. It is a criminal offence in Canada to remove a person’s organ or tissue by means of deception or through any form of coercion.

DECEASED DONATION

When no expression is known to have been made, it is acceptable for proxies to be approached regarding authorization for donation. The decision of a substitute decision-maker should be respected where legally authorized and medically possible. In some situations, families and substitute decision-makers should be made aware that DCD may not be possible. All decisions of a substitute decision-maker to cease life-sustaining therapy should be followed in accordance with relevant provincial or territorial legislation.

In uncontrolled situations (i.e., cardiac death has occurred but was not anticipated), the process of consent should be dictated by provincial and territorial legislation. In the absence of expressed donor intent or consent by a legally authorized substitute decision-maker, organ procurement should not proceed.
LIVING DONATION

Informed consent for living donations is both an ethical and legal concept. In the context of ODT, to obtain informed consent, physicians must provide adequate information to the patient or substitute decision-maker about: a) the potential short-term and long-term complications of living organ donations; b) potential outcomes and alternatives for the intended recipient with or without transplantation; c) other applicable options (e.g. donor paired exchange programs).

As remuneration could adversely affect the voluntariness of a potential living donor, the CMA supports current Criminal Code legislation that criminalizes the coercion of organ donation (i.e., organ trafficking). Similarly, the CMA discourages Canadians from participating in organ tourism as either a recipient or donor.

4. CONFIDENTIALITY AND PRIVACY

Prospective donors are strongly encouraged to discuss their choice with their family and/or substitute decision-maker to minimize uncertainty and possible conflict.

DECEASED DONATION

A person’s choice about whether or not he or she intends to donate organs and tissues after his or her death is individual and, like other health-related information, should be considered private. The right to privacy regarding personal health information extends beyond the declaration of death.

Current practice protects the privacy of both donor and recipient and does not allow transplant teams to inform either party of the other’s identity. The continuation of this practice is encouraged at the present time to protect the privacy of both donors and recipients.

LIVING DONATION

Whenever possible, potential donor and recipients should be cared for and evaluated by separate medical teams. In the case of non-directed donations, it may be necessary for some information to be shared between donor and recipient teams (e.g. recipient’s underlying disease and risk for recurrence); however, such information should be limited to what is medically necessary for making an informed choice. Conversely, the CMA recognizes that the choice and process of directed donation is

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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). Professor Timothy Caulfield also provides a summary of the law of consent for living organ donation here.
one that is deeply human, which is likely to result in the intersection of both donor and recipient pathways of care. In such cases, the same onus of confidentiality may not apply.

KEY RECOMMENDATIONS

1. The CMA supports the continued development and uptake by organ procurement organizations of the Canadian Transplant Registry and National Organ Waitlist to increase efficiency and combat inequities in organ allocation.

The CMA encourages that:

2. Physicians respect the decision of a patient that previously expressed a wish or commitment to be a donor after their death.
3. Physicians make every reasonable effort to be aware and considerate of the cultural and religious views of their patients as they pertain to OTDT. Likewise, institutions should provide continuing professional development opportunities for physicians to develop and apply cultural competency in contexts of OTDT.
4. Canadian medical schools provide mandatory training on organ donation.
5. Organ procurement organizations take every step to ensure that their members/staff are aware of and understand the legal framework supporting OTDT and implications in practice.
6. There is consistency across provincial laws regarding informed consent in contexts of OTDT to ensure guidelines that best support physicians and providers.
References


