ASSOCIATION MÉDICALE CANADIENNE | CANADIAN MEDICAL ASSOCIATION

CMA POLICY

ORGAN AND TISSUE DONATION AND TRANSPLANTATION

See also Background to CMA Policy on Organ and tissue donation and transplantation

RATIONALE

Organ and Tissue Donation and Transplantation (OTDT) is a rapidly changing area of medical science and practice. Organ and tissue transplantations represent significant lifesaving and life-enhancing interventions that require careful consideration by multiple stakeholders spanning medical disciplines.[1] Technological and pharmacological advancements have made organ and tissue transplantation increasingly viable for treating related medical conditions.[2] Changing social norms have also led to shifting perceptions of the acceptability of organ and tissue donation. Within this context, there is a need for renewed consideration of the ethical issues and principles guiding organ and tissue donation and transplantation in Canada.

The overarching principle that guides OTDT is public trust, which requires that the expressed intent either for or against donation will be honoured and respected within the donation and medical systems, and that the best interests of the potential donor are always of paramount importance; policies and mechanisms that guide OTDT should aim to maintain and foster that public trust. 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

This policy identifies foundational principles to address the challenges surrounding deceased and living donation. In conjunction with applicable laws and regulations in Canada, the Declaration of Istanbul, the World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplantation, and leading clinical practices this policy aims to inform physicians and other interested parties on the guiding principles of OTDT in Canada. 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

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Canadian specialty societies that deal directly with OTDT for up-to-date information and policy, as well as innovative techniques and approaches.

Guiding Principles

The practice of OTDT is of great value to patients and society. The CMA supports the continued development of greater capacity, efficiency, and accessibility in OTDT systems in co-ordination with comprehensive and compassionate end-of-life care for Canadians while acknowledging the importance of justice, informed consent, beneficence, and confidentiality to this practice.

1. Justice

There is a continuous need to improve the efficiency and effectiveness of OTDT in an effort to narrow the gap between demand and supply in what remains a scarce, lifesaving resource. The principle of justice should continue to guide the equitable allocation of organs and tissues in a manner that is externally justifiable, open to public scrutiny, and balances considerations of fairness (e.g., medical need or length of time on the wait-list) with medical utility (e.g., transplantation success). There should be no discrimination based on social status or perceived social worth. Lifestyle or behavioral factors should only be considered when clear evidence indicates that those factors will impact the medical probability of success. OTDT should also not rely on the patient's ability to pay; such actions are inconsistent with the principles that underlie Canada's publicly-funded health system. Of note, living donation to a loved one or acquaintance (via a directed donation) is regarded as ethically acceptable if potential donors are informed of all options, including that of donating in a non-directed fashion.

All levels of government should continue to support initiatives to improve the OTDT system, raise public awareness through education and outreach campaigns, and fund ongoing research, such that any Canadian who may wish to donate their tissues or organs are given every reasonable opportunity to do so. Potential donor identification and referral, while legislated in many jurisdictions, is an important area of continued development as failure to identify donors deprives families of the opportunity to donate and deprives patients of potential transplants.

To diminish inequities in the rates of organ donation between jurisdictions, federal and provincial governments should engage in consultations with a view to implementing a coordinated, national strategy on OTDT that provides consistency and clarity on medical and legal standards of informed consent and determination of death, and institutes access to emerging best practices that support physicians, providers, and patients. Efforts should be made to ensure adequate engagement with potential donors from communities that have historically had lower living donor rates to help reduce inequities in access to living donation. Policymakers should also continue to explore and appraise the evidence on policy interventions to improve the rates of organ donation in Canada – for example, see a brief overview of opt-in vs. opt-out donation systems in the background to this policy.

2. Informed Consent and Voluntariness

Organ and tissue donation must always be an autonomous decision, free of undue pressure or coercion. [a] By law, the potential organ donor, or their substitute decision-maker, must provide informed consent. Physicians should direct patients to appropriate resources if that patient has expressed interest to become a donor after their death. If a potential donor has not made an expression of intent for or against donation, substitute decision-makers, families, or loved ones may be approached to provide authorization for donation. It should also be noted that consent indicates a willingness to donate, but that donation itself hinges on factors such as medical suitability and timing.

End-of-life decisions must be guided by an individual's values and religious or philosophical beliefs of what it means to have a meaningful life and death. The autonomy of an individual should always be respected regarding their wish, intent, or registered commitment to become a donor after death. Input from family and loved-ones should always be considered in the context of the potential donor's wishes or commitments – these situations must be handled on a case-by-case basis with respect for cultural and religious views while maintaining the autonomously expressed wishes of the potential donor. Physicians should make every reasonable effort to be aware and considerate of the cultural and religious views of their patients as they pertain to OTDT. Likewise, Canadian medical schools, relevant subspecialties, and institutions should provide training and continuing professional development opportunities on OTDT, including both medicolegal implications and cultural competency.

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. Any exploitation or coercion of a potential donor must be avoided. However, remuneration from officially sanctioned sources for the purpose of reimbursement of costs associated with living donation (e.g., transfer to another location or lost wages during the procedure), may be considered when no party profits financially from the exchange. The CMA supports proposed amendments to the Criminal Code and the Immigration and Refugee Protection Act that criminalizes or otherwise seeks to prevent the coercive collection and transplantation of organs domestically and internationally (i.e., organ trafficking – see relevant guidelines on trafficking[3]). The CMA also discourages Canadians from participating in organ tourism as either a recipient or donor; physicians should not take part in transplantation procedures where it is reasonable to suspect that organs have been obtained without the donor's informed consent or where the donor received payment (from WHO Guiding Principle 7); however, in accordance with physicians' commitment to the well-being of the patient and the professional responsibilities relating to the patient-physician relationship in the CMA Code of Ethics and Professionalism, physicians have an obligation to treat a post-tranplant patient if requested after the patient has participated in organ tourism; physicians should be aware of any legal or regulatory obligations they may have to report a patient's organ tourism to national authorities, taking into consideration their duties of privacy and confidentiality to the patient.[4,5]

[a] *Criminal Code*, RSC 1985, c C-46, s 279.04(3)

3. Balancing Beneficence and Non-Maleficence

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 can benefit from the knowledge that they can potentially save lives after their own deaths. However, potential donors must not be harmed by the act of donating. In accordance with the Dead Donor Rule, organ or tissue procurement should never be the cause of death. 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. 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). Leading clinical criteria, in conjunction with legally prescribed definitions of death and procedures, should inform the determination of death before donation procedures are initiated.

DCD should be practiced in compliance with the regulations of individual transplant centers, relevant legislation, and leading Canadian clinical guidelines including the national recommendations for donation after cardiocirculatory death in Canada[6] and the guidelines for the withdrawal of life-sustaining measures.[7] Patients undergoing medical assistance in dying (MAiD) may also be eligible for organ and tissue donation – see relevant policy guidelines.[8]

Living Donation

Living donors are motivated to act primarily for the benefit of the recipient.[9] 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; living donation is not ethically acceptable where there is a material risk of death of the donor; living donors must 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.

4. Confidentiality and Privacy

Current practice protects the privacy of both donor and recipient and does not allow donation teams, organ donation organizations, or 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. In addition, healthcare providers should consider the privacy and confidentiality implications of practices employed throughout the assessment and post-operative periods – patient consent should be obtained for practices involving any loss of privacy or confidentiality (e.g. group education sessions, etc.).

Deceased Donation

A person's choice about whether or not they intend to donate organs and tissues after their 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.

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 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 necessary for making an informed choice. Conversely, the CMA recognizes that the choice and process of directed donation is one that is deeply personal, 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 given the choices of the donor and recipient involved.

Approved by the CMA Board of Directors December 2019

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