



ORGAN AND TISSUE DONATION AND TRANSPLANTATION (UPDATE 2015)

1. Introduction

Advances in surgical techniques, immunosuppressive drugs and supportive medical care have made possible a dramatic increase in the rates of successful transplantation of organs and tissues. In light of these developments, there is a need for renewed reflection on ethical issues concerning organ and tissue donation and transplantation and on principles relevant to the resolution of these issues.

The Canadian Medical Association (CMA) has developed this policy to provide guidance to physicians and other health care providers as well as to those who develop policy and protocols on issues of organ donation, increasing donation rates, defining and the processes for determining death, organ and tissue recovery and allocation and experimental protocols.

The provisions in this policy apply to all types of donation and transplantation. For the purposes of this policy and consistent with provincial and territorial law, there is a

requirement to separate obligations related to deceased organ/tissue donation practices from those related to the care of the living donor, and potential or actual transplant recipient of deceased or living donor grafts.

Extra considerations apply to experimental and innovative procedures (cf. section 10). When they become standard practice, the provisions in this policy will apply.

This policy is based on principles of general and professional ethics, many of which are codified in the CMA's Code of Ethics and related policy statements. Applicable principles are referenced throughout this policy where they may help to clarify and make explicit the reasoning behind a given statement.

2. General principles

2.1. A primary moral principle relevant to deceased organ and tissue donation is known as the "Dead Donor Rule." This principle stipulates that donors must be dead prior to organ/tissue procurement, that

organ/tissue procurement cannot be the cause of death, i.e., patients must not be killed by the act of organ or tissue retrieval. All attempts should be made to minimize harms to potential donors; especially live donors.

2.2. Policies and protocols concerning organ and tissue donation and transplantation must be based on the professional ethics that underlie the patient–physician relationship and the practice of medicine. Professional ethics incorporates the values of respect for persons, justice, beneficence, nonmaleficence, autonomy, confidentiality and privacy. In addition to responsibilities to individual patients, professional ethics encompasses more general responsibilities to society.

2.2.1. The primary obligation of physicians is to their individual patients. Related to this obligation physicians may also have responsibilities to the family members of their patients. The obligation to the patient has primacy over any obligations that may exist in relationship to the patient’s family members, although the interests of the two **may be** intertwined. Where the patient has consented to donate organs or tissues, the CMA encourages family members to respect these previously expressed wishes.

2.2.2 Physicians have responsibilities to society, which include promoting the fair use of resources, preventing harm and promoting health benefits for all Canadians. Because of their knowledge and expertise regarding the benefits of transplantation and consistent with widespread societal support for donation and transplantation in Canada, physicians are in a unique position to actively promote consideration of organ and tissue donation. In the event of a conflict between the physician’s responsibility to his or her individual patient and to society, the obligation to the patient should prevail.

2.3. Policies and protocols concerning organ and tissue donation and transplantation should be developed in recognition of the values of Canadians and the values that underlie our publicly funded health care system.

2.3.1. The expression of compassionate concern for others suffering from ill health and disability through voluntary, altruistic giving is a fundamental value for Canadians and for our health care system.

2.3.2. Free and informed decision-making about treatment is a fundamental value both in our health care system and in Canadian society more generally.

2.3.3. Privacy is a fundamental ethical value, both in health care and in Canadian society. Privacy refers to a zone of personal space and choice essential to the dignity of human beings that should be protected from unwanted intrusion or access. Informational privacy refers more specifically to the right of patients to control collection, use, disclosure of and access to their health information. In the context of organ and tissue donation, the right to privacy regarding personal health information should extend beyond the declaration of death.

2.3.4. Canadians are entitled to timely access, on equitable terms and conditions, to necessary and effective medical treatment. The responsibility to ensure the availability of and equitable access to medical treatment, including organ and tissue transplantation, is shared among governments, health institutions, health professionals and the general public.

3. Free and informed decision-making

3.1. Informed consent is a prerequisite for organ or tissue donation. Evidence of the free and informed decision of the patient, or of the appropriate proxy, must be

ascertained before organ procurement can begin.

3.2. The purpose for providing the opportunity to choose to donate organs or tissues may be to procure organs or tissues for transplant. Success in achieving this outcome should not be construed as a criterion for measuring the quality of the process of free and informed decision making. The quality of this process depends on whether the choice is adequately informed and voluntary and not on whether the outcome is a decision to donate.

3.3. Free and informed decision-making is a process requiring the exchange and understanding of information and absence of coercion.

3.3.1. In order for the choice to donate organs or tissues to be duly informed, prospective donors or their proxies should be provided with meaningful, understandable information pertinent to the choice. Normally, this will include information about (a) the benefits and risks of donation or transplantation, (b) procedures concerning the determination of death, (c) testing of organs and tissues to determine their suitability for transplantation, which may reveal unsuspected health risks in the prospective donors and their families, (d) measures that may be required to preserve organ function until death is determined and surgical procurement can occur, (e) what will happen to the body once death has been declared, (f) what organs or tissues they are agreeing to donate and (g) the protocol that will be followed in the event that the family objects to donation.

3.3.1.1. Prospective donors should be strongly encouraged to discuss their choice with their family to minimize uncertainty and possible conflict. Physicians should recognize that this is the preferred way of dealing with such conflicts.

3.3.2. Prospective donors or their proxies should be given the opportunity to ask questions about information provided to them about donation and should have their questions answered sensitively and frankly.

3.4. Where the wishes of the patient are known and there is no reason to believe that the choice to donate has not been adequately informed, is not voluntary or has changed, these wishes should be carried out. This should be clarified in law, policy and protocols. Under these circumstances, families should be encouraged to respect the patient's clearly expressed wishes.

3.5. Where the patient is no longer capable of making health care decisions and his or her wishes are not known or there is uncertainty about his or her wishes, the decision about donation should rest with the appropriate proxy, who should take into account everything that is known about the patient's wishes and values.

3.6. Protocols for free and informed decision-making should also be followed in the case of recipients of organs and tissues. Normally, this should include information about (a) risks of the procedure, (b) the likely short, medium and long-term survival, morbidity, and quality-of-life prospects, (c) alternatives to transplantation and (d) how organs and tissues are obtained.

4. Organ and tissue donation and transplantation at the societal level

4.1. The CMA recommends that a comprehensive, coordinated and sustained national strategy concerning organ and tissue donation and transplantation be developed in consultation and cooperation with all interested parties. The object of such a strategy should be to procure tissues and organs as necessary for medical care in a manner consistent with the values of

Canadians and with professional ethics. Ethical issues arising in connection with such a strategy and with the subject of donation and transplantation in general, should be resolved in an open process involving public dialogue informed by sound evidence. The CMA encourages governments to allocate resources for donor awareness through a continued and ongoing advertising campaign as well as a donor registration program, possibly tied to driver's license renewal.

4.2. Some organ and tissue transplantation procedures have become standard medical treatments and indeed treatments of choice for a variety of conditions. To the extent that lack of organs and tissues is a barrier to the provision of needed treatment, the medical profession has an obligation to promote policies and protocols to procure organs and tissues for needed treatment as consistent with professional ethics and the values of Canadians, including patient autonomy, free and informed decision-making, privacy and equitable access to needed medical care.

4.3. It is important that Canadians have the opportunity to become aware of the option of donation and be given the opportunity to choose whether to donate. Awareness and choice should be facilitated in a coordinated multifaceted approach by a variety of stakeholders and means, including media awareness and public campaigns. Physicians should provide their patients with the opportunity to make a choice with respect to organ and tissue donation, ideally in the context of an ongoing relationship with the patient and in advance of any crisis giving urgency to the choice; physicians should be reimbursed for discussions about organ and tissue donation with patients. However, in many provinces,

legislation enables offering families or surrogate decision makers the opportunity to donate at the time of the death of a loved one.

4.4. In the absence of consensus that "presumed consent" (i.e., the presumption that consent has been given unless there is evidence to the contrary) is consistent with free and informed decision making, the CMA considers that a policy of presumed consent is not recommended. Due to the absence of a societal debate on the policies of "presumed consent" and "mandated choice" (whereby all Canadians would be required to declare whether they wish to donate) and the concern both may contravene the requirement of patient autonomy and informed consent, the CMA does not recommend adoption of either policy at this point in time.

4.5. The CMA encourages further consideration of the advantages and disadvantages of a national donor registry that would collect and maintain a list of Canadian residents who have chosen to donate their organs or tissues. Any such registry must protect individual privacy and the individual's ability to control the collection, use and disclosure of and access to his or her health information for purposes other than registration. To the extent that such a registry would represent the fact of registration as evidence of free and informed decision-making, provisions must be in place to ensure that the decision is in fact adequately informed and to ensure that people can easily withdraw from the registry without penalty.

4.6. Policies and protocols to procure organs and tissues for transplantation must clearly state that patients should have their wishes about organ and tissue donation respected after their death.

4.7. The Canadian Medical Association

will work with other appropriate national organizations and other interested parties to ensure that medical students and residents receive adequate training in, and exposure to, the subject of organ and tissue donation during their training programs.

5. Organ and tissue donation and transplantation at the institutional and individual levels

5.1. Hospitals and other institutions in which donation and/or procurement occurs should develop policies and protocols consistent with this policy, make these known to physicians and other health professionals and providers of care working in the institution and ensure that adequate resources are available for their proper implementation. Hospitals and health care providers have an obligation to provide the opportunity to donate consistent with the societal expectations. Reasons that donation services, such as donation after brain death or donation after circulatory death, are not provided should be explained to families.

5.2. Physicians have an obligation to ensure that interactions at the bedside, including ones having to do with organ and tissue donation, are sensitive and consistent with ethical principles, in particular, with their fiduciary obligations to their patients. Thus, although the conditions at the bedside of dying patients may be strained it should be possible to routinely approach the patient or his or her family about options in a sensitive manner consistent with ethical principles relevant to the situation.

5.3. Approaching the patient or family requires a combination of knowledge, skill, sensitivity and comfort with the role. While the attending physician or member of the health care team known to the family may raise the subject of organ and tissue

donation with the patient or family if asked, this is best managed by a healthcare professional with highly specialized knowledge, skills and training in organ and tissue donation and consent requesting, including the representative from the organ donation organization. This may or may not be an individual within the hospital.. This discussion is best done early, when the patient or substitute decision-maker is more likely to be able to consider the facts.

6. Living donors

6.1. Directed donation from living donors to family member or close friends is acceptable.

6.2. Directed donation prohibiting donation to a specific group or class of persons is unethical.

6.3. In the case of living donors, special efforts may be required to maximize freedom from coercion. Methods may include talking to potential donors on their own, a “cooling off” period, psychological evaluation, etc. Individuals who are incapable of making informed decisions should not be considered as potential living donors except in very limited circumstances in accordance with **laws**, ethics committee review or established protocols.

7. Determination of Death

7.1. “Alive” and “dead” are boundary concepts – something can be dead or alive but not both; dying is a process and “dying” is a transitional concept. A difficulty arises if one wants unified criteria to determine when death occurs. Establishing unified criteria to determine death is difficult because the criteria used to determine neurological death cannot be used to determine cardiorespiratory death and vice versa.

However, medicine and the law have generally accepted the dual criteria for determining death; neurological (“brain death”) and cardio-respiratory (circulatory) classifications. Neurological death is characterized by catastrophic brain injuries that lead to the irreversible cessation of all clinical brain functions (“whole brain” death). In the absence of neurological functions, consciousness, brainstem reflexes and the capacity to breathe, the brain cannot sustain any cardiorespiratory function without supportive technologies in place. If neurological functions have ceased and the patient is on supportive technologies, when those technologies are withdrawn, cardiac and respiratory functions will cease since the brain is incapable of sustaining and integrating vital functions. Cardio-respiratory death, also called circulatory death, is characterized by the irreversible cessation of cardiac and respiratory functions; cardio-respiratory functions cease from causes other than loss of neurological functions. With circulatory death, the brain is still capable of sustaining consciousness, integrative and vital functions. The cessation of circulation and respiration leads to cessation of brain functions and death if circulation and respiration cannot or will not be re-established. The patient is dead if cardiac and respiratory function have not resumed spontaneously or in response to applied resuscitative interventions. In cases where the decision is made not to attempt resuscitation, cardio-respiratory functions may be reversible.

7.2. Provincial and Territorial law states the determination of death be made in accordance with accepted medical **practice**. Amendments or changes to the definition of or the criteria to determine death should include medical specialist. The CMA notes there are normative issues involved in

defining death and the sequela for declaring human death. Therefore the public should be engaged or aware of any discussions involving changes to the definition of or criteria to determine death as well as the permissibility of organ and tissue retrieval.

7.3. The criteria to determine death is a clinical matter that should be made according to widely accepted guidelines established by expert medical groups.

7.4. The CMA recommends that health care facilities develop protocols and procedures to educate and support patients and families who do not understand the criteria for neurological and circulatory death.

7.5. In order to avoid a conflict of interest, the physician who discusses resuscitative status, the decision to withhold or withdraw supportive technologies, the potential for organ or tissue donation and/or determines and/or certifies the death of a potential organ or tissue donor must not be directly involved in the organ or tissue removal, in subsequent transplantation procedures or be responsible for the care of potential recipients of the organs or tissues.

8. Donation after Cardiac Death

8.1. Organ and tissue procurement after circulatory [Donation after Cardiac Death (DCD)] death was reinstated to expand the organ donor pool and to fulfill individual wishes to donate under these circumstances. For DCD, cardio-respiratory death is defined as the irreversible cessation of circulatory and respiratory functions, i.e., pulseless and apneic. Irreversible is defined as the permanent cessation of circulatory function. Circulatory death may occur in one of two situations, controlled or uncontrolled cardio-respiratory death.

8.2. Uncontrolled circulatory death is characterized by an unanticipated cardiac arrest and resuscitation is attempted but is unsuccessful. If the patient fulfills organ donation criteria, donor status and proxy consent for donation is sought. When the prescribed time-to-death wait time has lapsed, organ preservation or procurement procedures are initiated.

8.3. Controlled circulatory death is characterized by a DNR/AND (allow natural death) order and the decision to withdraw supportive technologies from neurologically intact but ventilator-dependent patients. Controlled circulatory death is characterized by situations where death is anticipated. Based on the patient's values, the health care team and proxy decision makers agree to withdraw supportive technologies and forego resuscitation (DNR/AND – allow natural death order). Supportive technologies are withdrawn, the prescribed time-to-death post-cardiac arrest lapses and procurement procedures initiated. Organ preservation measures could be instituted prior to the declaration of death. Some protocols involve measures that preserve organs *in situ*.

8.4. Ethical and moral concerns with respect to the process of DCD remain. One ethical concern is whether the practice remains consistent with the dead donor rule (individuals must not be killed by organ retrieval). Some contend that if death is defined by irreversible loss of particular functions, DCD may contravene the dead donor rule since continued cardiac and neurologic functions are contingent on the consensual decision not to provide resuscitation and/or to withdraw supportive technologies. Resuscitation and/or supportive technologies could re-start or continue supporting organ and brain function; therefore functions are not

irreversibility lost (e.g. the heart is transplanted and re-started). This raises the concern that “irreversible” is used equivocally in the neurological and the circulatory definitions of death. When cardiac arrest has occurred and CPR is not provided, brain functions will cease. However, if preservation measures to perfuse organs are initiated, the brain may continue to function after cardiac arrest. This raises a third concern, the potential for harm. Given this potential for harm, a precautionary approach is advisable.

8.5. For the purpose of DCD, the CMA recommends that the minimum time-to-death should be 5 minutes post cardiac arrest.¹ The CMA recommends 5 minutes as current data suggests that the likelihood of cardiac auto-resuscitation or survivable residual brain function do not occur at this point. The CMA recognizes that there are moral and ethical concerns associated with the definition of death and the dead donor rule, and that robust data on auto-resuscitation are lacking. The CMA also recognizes that the supply of donor organs is limited, and that attempts to expand the donor pool and/or enhance donor organ function using organ preservation and perfusion interventions can raise further ethical concerns. As such, only patients whose proxy decision makers consent (in accordance with the patient's best known wishes) to DCD should be eligible.

8.6. Institutions that retrieve or transplant organs and tissues should be mindful that the public may consider brain death and DCD controversial. Institutions should have robust policies and procedures that included expansive disclosure and education of potential donors, families and surrogate decision-makers; transparency is essential.

¹ Reflects current accepted practice.

For example, policies, educational materials, disclosure and consent forms, recruitment scripts and discussions should explain the differences between controlled and uncontrolled DCD. Donors and/or surrogates should be aware that “irreversible” is contingent on choosing not to attempt and apply resuscitative interventions or to withdraw supportive technologies. They should also be informed whether or not the heart itself will be retrieved and transplanted. Donors and/or surrogates should be aware of risks and benefits or organ preservation interventions prior to death and provided informed consent to those interventions, e.g., whether organs are cooled in situ and/or if in order to perfuse organs, catheters will be inserted before and or after the declaration. Donors and/or surrogates should know the length of time that will pass between declaration of death and procurement of organs and tissue. The decision to donate must be free and adequately informed (see section 3).

9. Justice in the allocation of organs and tissues

9.1. There should be explicit policies open to public scrutiny governing the management of waiting lists for organs and tissues.

9.2. Policies governing the management of waiting lists should promote efficiency and fairness. Criteria that should be considered in allocating organs and tissues include severity of medical need, length of time on the waiting list and medical probability of success measured by such factors as type of disease, other complications and histocompatibility. There should be no discrimination based on standard human rights grounds, social status, lifestyle or behaviour. However,

organ transplant candidates routinely have their waiting list “activation” delayed or denied due to lifestyle or behavior factors if these factors are medically relevant criteria for organ allocation.

9.3. Special public appeals for organs for a specific recipient **must be discouraged** because they raise concerns of justice; for example, the designated recipient may not be the most appropriate to receive the organ based on explicit criteria (e.g., severity of need or probability of benefit).

Public appeals are perceived to be a means to jump the queue. Public appeals are different from directed donation from live donors as potential donors do not have a pre-existing relationship with the recipient.

9.4. Directed donations of organs and tissues from deceased donors to a family member may be appropriate in limited circumstances, providing that the decision to donate was fully informed and voluntary and the criteria for allocating organs and tissues are met (see 9.2).

9.5. Payment for organs and tissues for donation and transplantation **is** prohibited. Paying for organs and tissue is prohibited because access to needed medical treatment based on ability to pay is inconsistent with the principles of justice that underlie our publicly funded health system and because the financial incentive may compromise the voluntariness of the choice and the altruistic basis for organ and tissue donation. This does not exclude reasonable reimbursement of expenses such as those incurred in procurement, transport, processing, preservation and implantation. In addition, the advertisement of organs and the use of organs suspected to have been obtained through commercial transaction is prohibited.

10. Experimental and newly developing transplantation procedures

10.1. Although many transplantation procedures have become standard medical care for a range of medical conditions, others, such as the use of embryonic, fetal, reproductive, brain and nonhuman tissues and organs, are experimental and/or ethically controversial and require further research, safeguards, guidelines and public debate. The CMA encourages the development of national guidelines consistent with the values of Canadians to govern these practices.

10.2. Experimental procedures and new devices require protocols, including ethics review, different and more rigorous than those for standard medical procedures. However, experimental procedures and new devices can expand the numbers of available organs. One example is a portable device that can perfuse organs for transport to transplant centers.

10.3. Xenotransplantation raises special ethical and scientific issues, particularly in light of the risk of cross-species transmission of viruses and other pathogens. Extensive public debate about ethical and scientific issues such as xenotransplantation, other experimental procedures or novel devices should occur to ensure that developments in this field are consistent with the values of Canadians.