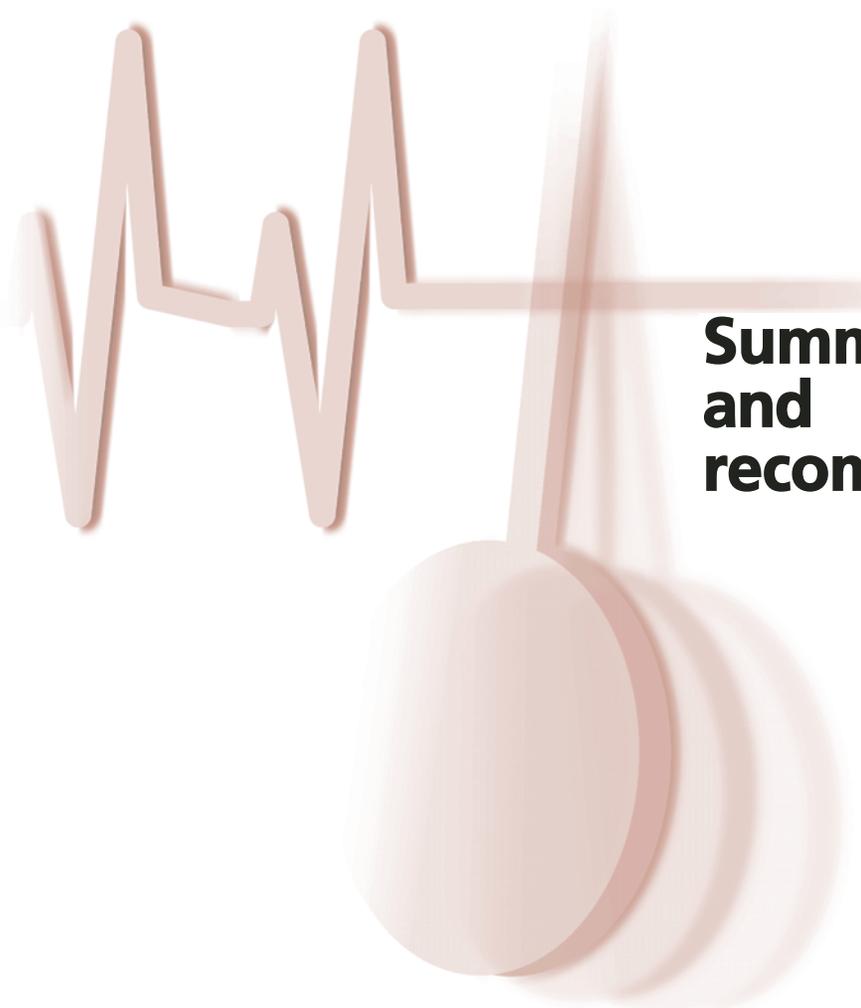


POSITION STATEMENT ||||

Organ Donation and Transplantation: Ethical Dilemmas Due to Shortage



**Summary
and
recommendations**

Commission de l'éthique de la science et de la technologie

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List of Acronyms

ACOT	Advisory Committee on Organ Transplantation (United States)
AMA	American Medical Association
BDC	Brain death criteria
CAOD	Canadian Association of Organ Donations
CCDT	Canadian Council for Donation and Transplantation
CCNE	Comité consultatif national d'éthique (France)
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CDC	Cardiac death criteria
CEST	Commission de l'éthique de la science et de la technologie (Québec)
CETSQ	Conseil d'évaluation des technologies de la santé du Québec
HIV	Human immunodeficiency virus
HLA	Human Leukocyte Antigen
MSSS	Ministère de la Santé et des Services sociaux (Québec)
NHBD	Non-heart-beating donation
ONT	Organización Nacional de Trasplantes (Spain)
WHO	World Health Organization

Summary and Thematic List of Recommendations

This CEST position statement examines the ethical issues raised by vital organ (heart, lungs, kidneys, pancreas, liver) donation and transplantation. Scientific and technological progress has made transplant medicine a widespread practice in developed countries. However, the number of organs available for transplant cannot meet the needs of all patients awaiting transplants, and so various strategies have been envisioned to address the organ shortage. The Commission therefore paid special attention to the ethical issues raised by these strategies.

Some Background

Theoretical context

The concept of donation is central to the Commission's analysis and is at the heart of the issues addressed by this position statement. Fundamentally, donating is a selfless act; nothing is sought in return. However, while donating guarantees nothing in return, not only do donors often benefit nonetheless, but they can reap a reward greater than the donation itself. In the act of donating, the nature and characteristics of the bond between donor and recipient are key. In this respect, donation is not neutral: it affects this relationship and either nourishes and strengthens it, or weakens and threatens it.

Given that organs are donated, the Commission's thoughts on consent, donor and recipient anonymity, living donor transplants, and organ commercialization must bear in mind what organ donation is and what it should be. But, before it could even address these issues, the Commission had to consider the ethical acceptability of organ donation. It noted that the practice is widespread and subject to well-established standards, and that it raises no objections from society, where everyone is entirely free to donate organs, or to receive organs if their health so requires, without any obligation of reciprocity. Given the context of organ donation and transplantation in Québec, the Commission believes a fair balance has been struck over the years between scientific and medical progress and the ethical acceptability of their applications. It therefore undertook its deliberations on the premise that organ donation is ethically acceptable.

Historical context

Organ transplants still remain a scientific and technical miracle. But their current success rate means they are no longer the difficult and spectacular event of the past. Historically, transplant medicine is relatively young and its first successes date back to 1954, with the first successful kidney transplant. After a slow and troubled start, research spurred numerous discoveries in immunology and blood and tissue compatibility. As it has largely succeeded in mastering organ rejection through immunosuppressants, vital organ transplantation has today become an accepted treatment for organ failure.

Standards context

The Commission reviewed several standards documents governing organ donation and transplant practices at the provincial, national, and international levels. However, unlike most countries, Canada and Québec do not have specific laws governing organ donation and transplantation. The practice is nonetheless well regulated by a series of standards documents that set out the rules of good practice, both from a scientific and deontological perspective. In Québec, the *Civil Code* could be said to provide the primary legal framework.

Economic context

Since it has a universal healthcare system whose costs are absorbed by all taxpayers, Québec must constantly make healthcare choices. Scientific and technological advances increase overall treatment options, but also strain the system's human, material, and financial resources. Transplant medicine is one of many medical specialties whose costs continue to spiral as we seek to meet the needs of an aging population and provide treatment that will give patients a better quality of life or save them from an early death.

The Commission neither questions the legitimacy of transplant medicine, nor accords it special status among other healthcare needs. The matter is not for it to decide. It nonetheless believes that a concern for fairness must prevail and that access to transplants must be improved for those in need, with no discrimination on grounds other than medical. The Commission is fully aware that compromises are necessary to improve access to transplants in times of tight healthcare funding, and in this regard invites the Québec government to examine the situation together with healthcare officials and the population.

Québec context

Generally, organ donation and transplantation are growing in Québec, despite the lack of resources in hospital settings. Among the major players in the field—other than those directly involved in the medical act of transplantation through the healthcare network—Québec-Transplant is notable for the key role it plays in all organ donation and transplantation activities. The organization was behind the creation of a resource nurse service devoted specifically to supporting families with loved ones about to die and facilitating the organ and tissue donation process. Numerous charitable organizations also play an important role for patients awaiting organ transplants and for promoting donation among the population.

Despite encouraging statistics showing a certain increase in organ donation over the years, the organ shortage remains serious. This shortage further complicates the ethical dilemmas for the Commission. The organ shortage phenomenon is relatively well documented, and the Commission is able to state that there are too few organs available for the number of patients awaiting transplant, as well as too many patients who die before receiving the organ they need to survive. It should be stressed that Québec is doing extremely well and is far and away first among Canadian provinces in terms of cadaveric donors per million of population. Unfortunately, Québec is well under the Canadian and U.S. averages when it comes to living donors, a situation that requires further analysis if we are to improve it.

Technical Aspects and Ethical Issues

Cadaveric donation based on brain death criteria (BDC)

Two types of organ donation are currently practiced in Québec: cadaveric donations based on brain death criteria (BDC) and living donations. BDC cadaveric donations date back to the early 1970s, when brain death criteria were defined. These criteria enable physicians to pronounce patients dead who have suffered serious neurological trauma, while maintaining their cardiopulmonary function to prevent organ deterioration.

The entire process from identifying a potential donor to harvesting the organs raises ethical questions regarding support for families, procedural transparency, and donor anonymity. The **issue of support** for families as they wait for brain death poses serious challenges for healthcare professionals, who must interact with the families and are often unprepared to deal with this type of situation and propose organ donation as an option. The **issue of transparency** raises the problem of conflict of interest (real or potential) between the best interests of the donor and recipient and the need for separate teams, one responsible for keeping patients alive and later declaring brain death and another responsible for organ harvesting. With regard to the **issue of anonymity**, the established practice is to preserve donor and recipient anonymity so that neither knows the identity of the other. The Commission notes that communicating through third parties as under the current rules is most often mutually beneficial and that the danger of complications arising (e.g., expectations or requirements of recipient or donor's loved ones) is generally low. However, the Commission also notes the importance of reciprocity in the donation process and the wellbeing it can afford the persons involved. It would therefore like a door to be kept open for consenting adults (recipients and families) to eventually meet and—in some ways—finalize the donation process.

Living donation

As a general rule, when someone agrees to donate a kidney or part of an organ, it is for a family member (genetic relationship) or loved one (emotional relationship) such as a spouse or friend. Though the practice could partially alleviate the organ shortage, living organ donation is rare in Québec compared to Canada and the U.S. This type of donation is quite unique, if only for its contravention of the “do no harm” principle: donors do not benefit physiologically from their donation. However, the Commission acknowledges that this type of donation may offer donors psychological benefits, including the ability to save the life of a loved one or improve their quality of life. Given that anonymity cannot be ensured in living organ donations—due to donors and recipients being genetically or emotionally related—the Commission believes medical teams should always wait for donors themselves to express their desire to donate an organ if a loved one needs it. Physicians should therefore not place any pressure on the family or loved ones of the patient. And they have the fundamental duty to inform potential donors of possible physical and mental risks to help them make an informed choice.

The authenticity of the donation must also be verified through a physical and psychological assessment of the donor; in fact, this is a transplant center requirement. This means checking donor and recipient compatibility (physical assessment), but also the authenticity of the donor's commitment (psychological assessment) and the absence of pressure from the patient or the patient's circle. The assessment is to help determine the degree of physical and psychological risk organ donation poses to the donor.

The issue of living organ transplant safety is also of concern to the Commission. In the case of kidney transplants, results are better with living donors than with cadaveric donors, both in terms of patient survival and transplant duration. The Commission therefore recommends recognizing the value of living organ donation for kidney transplants and developing good practice guidelines in this regard. However, it seems risky to broaden this recommendation to liver and lung lobe transplants. In this respect, the Commission recommends undertaking research to compare the results of liver and lung lobe transplants from living and cadaveric donors. This would help determine if living donation is as safe for liver and lung lobe transplants as it is for kidney transplants.

It is crucial that donors be treated fairly. Donors have reportedly been discriminated against by their employers for missing work and other reasons. The Commission believes that, just as with the Jurors Act¹, it is unacceptable for an employer to fire, suspend, or move employees; subject them to discriminatory measures or reprisals; or impose any other sanction for having donated an organ. Accordingly, it recommends that the Québec government ensure that living donors are at no time subject to discrimination based on their donation and its aftereffects.

Currently, living donors must incur certain expenses as part of the donation process. For the Commission, reimbursing living donors for these expenses is a question of fairness. It seems insensitive in the eyes of the Commission to ask donors to cover expenses engendered by an altruistic act on their part. Because it does not profit the donor, reimbursing expenses incurred by living donors does not constitute what the Commission considers to be organ commercialization. The Commission therefore recommends that the government explore the possibility of setting up a reimbursement system to promote fairness toward donors, while preserving the altruism of the act.

Cadaveric donation after cardiac death or based on cardiac death criteria (CDC)

The growing gap between the number of organs available and the number of patients awaiting transplants requires that strategies to enlarge the donor pool be explored. One option is using cardiac death donors. Each year in hospitals, many patients die who have suffered serious neurological trauma, but who do not meet all brain death criteria. Life support measures keep these patients alive. However, if the family and physician agree on ending such treatments, the patient is taken off mechanical support and dies in the minutes or hours that follow. Death is then declared based on cardiopulmonary arrest criteria. Organs could be harvested from some of these patients. Yet Canada currently has no organ harvesting protocol for CDC cadaveric donors.

In the Commission's view, this avenue could be explored, but with caution, as it raises many ethical questions. The **issue of consent** takes on very special significance depending on whether potential donors are conscious or unconscious. In the latter case, the burden of organ donation consent often falls on loved ones. The **issue of transparency** concerns the possibility of a conflict of interest when healthcare professionals are responsible for decisions regarding both treatment cessation and organ harvesting. This issue is the subject of a Commission recommendation in order to clearly separate the two decisions. The **issue of safety** concerns the methods used to preserve the quality of the organs in the event that donor death has not yet occurred, but is imminent. On this matter, the

1. Jurors Act (R.S.Q., chapter J-2, 2001, c. 26, sect. 131).

irreversibility of death drew the Commission's attention, which noted a lack of consensus on the issue and has formulated a recommendation to this effect.

Should a cardiac death donor organ harvesting program be started, the Commission believes a much more extensive analysis of ethical and technical issues and organ preservation methods is needed. Such an investigation must occur to prevent the commodification of the human body and remedy the current lack of consensus on the subject. The Commission sees using CDC donors as a strategy that could help increase donor numbers. Nonetheless, it believes this avenue cannot be followed without in-depth scientific and ethical deliberations and without consultations with the population and healthcare representatives who would be affected by such a practice.

Consent and Raising the Subject with Families

Consent models

Consent is mandatory before organs can be harvested from cadaveric donors. Consequently, consent is a major factor in efforts to increase the number of organs available for transplant. There are two main consent models (explicit and presumed) and several ways to approach them. The Commission has examined two of them in this position statement: mandated choice and the creation of a registry.

The **explicit consent** model means that, to consent, individuals must clearly express their desire to donate their organs at death. This is the model used in Québec. To give consent, you need only sign and place a sticker on the back of your health insurance card. Ethically, the explicit consent model respects the autonomy of each individual and their freedom to choose to donate organs. This model also fosters respect for the integrity and inviolability of the person, the right of control over one's body, and the right to self-determination. It even lets one choose not to donate organs. Lastly, it upholds the spirit of voluntary donation in all its generosity.

The **presumed consent** model requires those who do not wish to donate their organs to express their refusal and not their consent. In the absence of refusal, organ donation consent is presumed and organ harvesting is authorized at death. The presumed consent model stresses social solidarity, but its underlying goal is to maximize the number of organ donors. However, experts are divided on the impact of presumed consent on the number of organ donations.

Complementing these models are scenarios that could also increase organ donor numbers. The Commission looked at two of them: mandatory declaration and the creation of a registry. **Mandated choice** is a mechanism by which all those deemed able to consent would be obliged to declare if they wished to donate their organs. This strategy plays off the fact that, in all Western societies, a strong majority of people favor organ donation. However, this belief does not always equal consent. In the absence of the donor's clearly expressed wishes, the greatest obstacle to organ donation is the family's refusal. If everyone clearly makes their wishes known, the number of donations should, in theory, increase. The creation of a **registry** consists of gathering in a central database the names of those who have agreed (through explicit consent) or refused (through presumed consent) to donate their organs at death. However, the government's creation of a mandated choice plan or registry offers very few benefits in relation to resulting risks (increase in refusals, poor public participation) and inconveniences (updating, high management costs).

The Commission believes that the current explicit consent model is proven and continues to reflect the fundamental values of Québec society. For the moment at least, the Commission does not consider the two scenarios cited to be viable solutions for increasing the number of organ donations.

Raising the subject with families

Once an individual is brain dead and has been identified as a potential donor by healthcare professionals, the latter contact the family. They do so first to support the family in the mourning process, but also to discuss the possibility of organ donation. The Commission has identified three fundamental values that must guide healthcare providers in this process: respect for families, autonomy of families, and trust.

Respect for families is crucial. It is important to remember that the family of a potential donor is above all a family with a member who has just died or is on the verge of dying and that is beginning the mourning process. Thus, when the subject of organ donation must be raised, the Commission believes it is key for those responsible to maintain a neutral tone that does not convey that consent is expected and that a refusal would be disappointing. The **autonomy** of families in their decision making is another equally important value. Underpinning the recognition of families' autonomy is the need to give them all the information they need to make an informed choice. Families find themselves in a hospital setting that is governed by its own standards and has developed a specific vocabulary, practices, and protocols over time. Healthcare professionals must therefore try to make family members understand how this universe works without seeking to impose their point of view. The value of **trust** must also be at the fore. By fostering respect for the autonomy of families, the Commission believes a relationship built on trust can develop between healthcare professionals and the family and prove conducive to organ donation consent. However, to strengthen this trust, donor families must also be assured that they will receive the followup to help them live with their decision.

The Commission wishes to commend the Québec-Transplant initiative to train resource nurses at numerous hospitals across the province. These nurses are responsible for helping identify potential donors, supporting families throughout the organ donation process, and providing followup.

Organ Distribution

The Commission also looked at organ distribution among patients awaiting transplant. Organ distribution involves two processes: the selection of transplant candidates and the assignment of organs. Both must be clearly distinguished.

Selecting transplant candidates

Candidate selection is the process by which, following a specialist's diagnosis, a patient's name is or is not added to the official Québec-Transplant waiting list, which is used for organ assignment purposes. With respect to selecting transplant candidates, the central issue is still deciding which criteria should be used to assess potential candidates. Medical factors² generally seem to carry the most weight in determining who should be put on

2. Some examples of medical factors: HIV positive, presence of cancer, a multisystem illness, hepatitis positive, the degree of clinical incapacity, and general health

the waiting list, regardless of the type of transplant organ. However, psychosocial factors³ are also considered in transplant candidate assessments, and the Commission has noted that these factors cannot be given equal weight in all transplant cases.

Two philosophies underlie the main transplant candidate selection trends, each with major differences in the weight they accord various medical and psychosocial factors. The first (mainly used for heart, lung, liver, and pancreatic transplants) subjects candidates to tighter screening so that those placed on the waiting list are those who have the greatest chance of transplant success. The second (mainly used for kidney transplants, where one can wait a certain time for a transplant thanks to hemodialysis) seeks to give the maximum number of patients a chance at receiving a transplant. While the first philosophy is mainly aimed at efficiency, the second strives for fairness above all. Each transplant center or team has its own transplant candidate selection policies and follows the philosophy it deems the most suitable. Yet differences are minimal, and each transplant team or center's philosophy is in keeping with the most recent scientific and technological developments. The Commission wishes to see transplant centers and teams working from one clear and similar assessment grid, and has developed a recommendation to this effect.

Organ distribution

In Québec, Québec-Transplant and transplant centers and teams share responsibility for distributing organs and maintaining the waiting list. The order in which recipients appear on the list is determined based on the transplant organs available and organ distribution criteria. Organs are distributed differently depending on the organ harvested. These differences are explained by the inherent features of the organs themselves. For example, it is unthinkable to distribute hearts as one would kidneys, as the two organs do not serve the same role and the body does not accept them the same way. Various protocols adapted to each organ have therefore been established to provide a proper distribution method in line with the latest scientific data.

The Commission believes that safety is crucial in organ distribution. Organ harvesting, processing, conservation, storage, and distribution must all be closely governed by strict organ quality and transplant safety standards. The Commission has nonetheless raised a series of concerns it shares with Ministère de la Santé et des Services sociaux (msss) and believes require a priority response. The Commission prefers to abstain from choosing unequivocally between transplant efficiency (life expectancy and the degree of post-transplant quality of life improvement), safety, and fairness in organ distribution. Instead, it has chosen to address the three issues simultaneously through its recommendations to strike a necessary balance.

Other Methods to Alleviate the Organ Shortage

In a sense, the Commission's decision to address consent models, manners of approaching families, and the idea of using cardiac death donors already shows a focus on alleviating the organ shortage. However, other strategies also exist, such as raising awareness among healthcare professionals and the population, organ commercialization, xenotransplantation, and the development of artificial organs.

3. Some examples of psychosocial factors: candidate motives, understanding of transplant risks and benefits, presence of a support network, willingness to follow an anti-rejection medication regimen.

Raising awareness about organ donation

In the case of **hospital staff**, lack of awareness has serious consequences for it means that not all potential donors are considered for organ donation. The Commission believes that resource nurses must be given the resources they need to effectively and efficiently raise awareness in hospitals. Moreover, noting the current deficiencies in training for healthcare professionals on matters of death and mourning and the specific issue of organ donation, the Commission recommends providing future workers with better basic training and healthcare professionals with more professional training on the medical and psychological aspects of organ donation and transplantation.

In terms of **raising public awareness**, the Commission's consultations helped it gauge that efforts in this area should stress the social value of transplants and lead to awareness campaigns promoting a positive image of transplants. It is also vital to break down taboos and certain prejudices about organ donation and transplantation. The Commission recommends that Québec-Transplant be given special responsibility for public awareness measures.

Organ commercialization

Organ commercialization, another strategy, mainly refers to providing compensation for organ donation through various means or profiting financially from the sale of organs. The Commission has addressed two forms of commercialization: compensation and remuneration.

It defines organ donation **compensation** as paying a sum of money to the family of a cadaveric donor or a third party designated by the deceased or granting a tax break. These incentives are aimed at encouraging people to consent to organ donation and families to opt for donation on the death of a parent. For the Commission, **remuneration** is more akin to a monetary transaction and involves living donors. It consists of paying someone a sum of money in return for the donation of a kidney or part of another organ. These two forms of organ commercialization are generally condemned and banned by the international community.

The Commission believes that any form of compensation or remuneration for organ donation is ethically unacceptable. Organ commercialization leads to commodification of the human body and runs counter to human dignity. It also limits the autonomy of potential donors and their families by overly pressuring them to donate organs. In the Commission's view, it is important to foster individual autonomy, as this value is not only a barrier to undue manipulation, coercion, and pressure, but also a precondition of democracy. In addition, the Commission believes organ commercialization would have harmful effects on public trust in the organ donation and transplant process, on the quality of organs harvested, and on donor and recipient health. The Commission believes that organ donation (cadaveric or living) must be founded on selfless motives that categorically exclude any form of commercialization and, it goes without saying, trafficking.

Xenotransplantation

In a society unable to meet the organ shortage, scientific research has turned toward animals to study whether they may be able to provide organs for transplantation into humans. Though xenotransplantation seems to hold out considerable promise (shorter

wait times, better recipient preparation), it comes with concerns (human health risks, high cost). The Commission therefore wished to quickly examine some of the ethical issues tied to xenotransplantation, such as social acceptance, consent, animal wellbeing, and biosafety.

If xenotransplantation becomes safe, its social acceptance will probably vary by society and culture. The use of animals for human purposes already raises its share of questions. In addition, transplanting animal organs into the human body has a symbolic meaning that could have psychological effects on recipients and their loved ones. The Commission cannot stress enough the need to inform and consult with the population on the issue of xenotransplantation, but also to give it the tools it needs to take an informed stance on the subject. The Commission fears that going ahead with xenotransplantation without first ensuring it is socially acceptable would risk stigmatizing or even discriminating against animal organ recipients. What's more, it believes that the will to live should not lead people and society in general to shortchange reflection on the ethical, social, psychological, and symbolic aspects of xenotransplantation.

Consent to clinical xenograft trials or the xenograft itself not only involves the consenting person, but also their family, loved ones, and, ultimately, society as a whole. The risks associated with xenotransplantation—notably infection—can affect the consenting person as well as everyone around them. The Commission believes it is important to monitor animal organ recipients to limit the risks tied to this practice if it is adopted.

In terms of **animal welfare**, the idea is generally accepted today that animals deserve a certain degree of respect and should not be seen only as a way to meet human needs. Xenotransplantation runs counter to this. Xenotransplantation's potential success necessarily entails the raising and slaughtering of numerous genetically modified animals (which itself raises ethical issues), whether for experimental purposes or to provide organs for waiting patients. In concert with other international organizations, the Commission is currently of the opinion that every effort should be made to minimize the suffering of these animals, that special attention must be paid to use only the number of animals needed, and that animal organ donors be treated with respect.

The Commission considers **biosafety** an issue with several ethical and legal dimensions. From an ethical standpoint, the Commission believes it would be irresponsible and unacceptable to proceed with xenotransplantation as long as infection risks are not fully known—both by the competent health authorities and the population—and kept to a level deemed acceptable. The Commission's reservations have been framed in a recommendation to the competent authorities. It also wishes to stress the difficulties of legislating such a practice.

Artificial organs

Biomedical engineering exploits can make us dream of the day when it will be possible to build mechanical replacement parts for the human body in workshops. The latest research tends to show, however, that the era of complete, self-sufficient, and implantable artificial organs will not be arriving anytime soon. The Commission nonetheless chose to provide a quick overview of current artificial organ technology and examine two of the main ethical issues this technology raises: the distribution of resources and the robotization of the human body.

In terms of resource distribution, the Commission believes it is crucial to stress that universal access to frontline healthcare is a given in Québec society that must be preserved. While it acknowledges the importance of funding artificial vital organ research, the collective choices that must be made in this respect give the Commission pause, given the staggering costs of replacing human organs with artificial organs for all waiting transplant patients. Currently, available technologies can keep patients alive as they wait for an organ or prolong their life expectancy, but they can only be used sparingly due to their cost.

Concerning artificial organs, there are still numerous obstacles to overcome and the technology could also be very expensive for eventual users. Moreover, the idea of artificial organ transplants has major ethical and philosophical implications. The Commission believes it would be prudent to think about these issues before proceeding too far in the development of artificial organs.

* * *

Organ donation is both a tragic and joyous event. It is tragic because it means the death of a person and mourning for their loved ones. But it can also be joyous, as it helps save lives and rekindle hope in seriously ill patients. And it is partly for these reasons that organ donation and transplantation are emotionally charged issues that raise many ethical dilemmas. The Commission undertook its deliberations with a great deal of interest and respect. It hopes it has succeeded in shedding a thoroughly ethical light on the subject and striking a fair balance in its assessment and hierarchization of the values in question.

Thematic List of Recommendations

As part of its position statement on the ethical challenges of organ donation and transplantation in times of shortage, CEST has formulated a number of recommendations for the various political and institutional players involved. The Commission's ten recommendations break down into two groups: two recommendations address organ donation and transplantation in general, and the eight others specifically address strategies to alleviate the organ shortage.

To provide a better overview of the core of its recommendations, the Commission has grouped them below in an order different from the one used in the position statement, where they follow the text's logical order. They are listed based on the subjects addressed and provide a look at the sometimes contradictory values underpinning them.

General Recommendations

Cadaveric donor anonymity

A question of confidentiality and recognition: While recognizing the merit of current policies for protecting donor and recipient anonymity in cadaveric donations, but considering nonetheless that the door should be left open for consenting adults (recipients and donor families) to eventually meet if both parties so desire,

The Commission recommends

that Québec-Transplant and physicians involved in the organ donation and transplantation process—

- a) Maintain the current donation anonymity policy
- b) Consider requests for the organ donor's family and the recipient(s) to meet and, if both parties agree, clearly inform the parties involved of the risks associated with such a practice and ask them to sign a consent form to this effect
- c) Follow up on and assess the benefits of these meetings (R1⁴)

Transplant candidate selection criteria

A question of transparency and fairness: To encourage transparency and the development of criteria that ensure all those in need of a transplant are treated fairly,

The Commission recommends

that transplant centers and teams ensure that—

- a) Transplant candidate selection criteria are clear and information is easily accessible
- b) They have a written policy on the issue
- c) A multidisciplinary team work from a transparent candidate selection procedure (R7)

4. This number corresponds to the order in which recommendations appear in the text.

Recommendations on Strategies to Alleviate the Organ Shortage

Increasing living donation

A question of donor generosity and safety: Whereas the success rate of living donor kidney transplants is higher than that of cadaveric transplants, but recognizing the lack of sufficiently broad studies on the long term health of living donors and recipients of kidneys or other vital organs suited to this type of transplant,

The Commission recommends

that transplant centers in cooperation with Québec-Transplant—

- a) Recognize the value of living donor transplants in the case of kidney transplants and draft good practice guidelines in this regard
- b) Follow up with donors and recipients to track transplant organs and compile information on the long term health of donors and recipients in living donor transplants (R2)

A question of fairness: Whereas living donors who generously donate an organ may sometimes suffer reprisals from their employer and must cover various expenses related to the donation,

The Commission, while reiterating its opposition to organ commercialization (remuneration and compensation), recommends

that the Québec government—

- a) Ensure living donors are at no time discriminated against based on their donation and its consequences
- b) Explore the possibility of developing an expense reimbursement system for living donors, and set limits (R3)

Cadaveric donation based on cardiac death criteria (CDC)

A question of transparency and trust: Whereas using CDC donors could help increase the number of organs available for transplant, but recognizing the scientific and ethical limitations of implementing such an approach and the concerns it may raise among the population and hospital staff,

The Commission recommends

that, prior to drawing up a CDC donor protocol, the federal and provincial governments—

- a) First inform and consult with the population and healthcare representatives to ensure the transparency of the protocol development process and prevent negative effects such as population mistrust of the entire organ donation process
- b) Ensure that such a practice is governed by standards in line with recognized and fundamental medical values and ethics to guarantee its legitimacy
- c) Ascertain that such a procedure is legal
- d) Consider running pilot projects in centers with the necessary expertise and equipment and that have already shown their ability to identify potential donors (R6)

A question of donor dignity and respect: To provide dying patients with all the care they need and ensure a free and informed decision on treatment cessation and the declaration of death, independent of any pressure to consent to organ donation,

The Commission recommends

that, in the event that a CDC donor organ harvesting program is developed and in view of protecting patient autonomy, healthcare providers caring for the donor raise the issue of organ donation with the patient or their family only after the decision to stop life-sustaining treatments has been made and confirmed. (R4)

A question of respect for the donor's life and preserving the organs for harvest: Whereas there is currently no consensus on the amount of time physicians should wait between cardiopulmonary arrest and pronouncement of patient death, and that any such pronouncement must be based on clear scientific and ethical criteria,

The Commission recommends

that, even before developing a CDC donor organ harvesting program, the competent authorities set a time lapse between cardiopulmonary arrest and the pronouncement of death that would be scientifically and ethically acceptable and justified. (R5)

Raising awareness of organ donation

A question of openness to organ donation for healthcare professionals: Having been informed of the deficiencies that seem to exist in the awareness and training of healthcare professionals working in transplantation,

The Commission recommends

that the various players involved in an educational capacity ensure that—

- a) The appropriate college and university study programs devote teaching time to organ donation and transplantation and their ethical dimensions
- b) Healthcare professionals attain a truly broad understanding of organ donation and transplantation (ethical issues, death determination criteria, identifying potential donors, donor life support, approaching families, mourning, ethnocultural communities, etc.) and organize more professional training activities in this regard to address current deficiencies (R8)

A question of public solidarity: Whereas public awareness efforts must stress the social value of transplantation and its positive effects, and that shortcomings subsist in this regard,

The Commission recommends

that the Québec government give Québec-Transplant the mandate to raise public awareness in collaboration with other organizations, and award it the funding to this effect (R9)

Xenotransplantation

A question of prudence: Given the known and possible infection risks, the numerous ethical issues requiring in-depth study, and the social acceptance needed to implement such a practice,

The Commission recommends

continuing the moratorium on xenotransplantation and any related clinical trials as long as conclusive scientific results on animal models have not been obtained (R10)

Appendix 1

Three-stage consultation on organ donation and transplantation

In preparing its position statement on organ donation and transplantation, the Commission consulted with the general population and various players involved in the field. This consultation took three forms: group interviews by a specialized firm, a general online consultation, and a mini phone survey as part of the Statmédia survey in spring 2004.

Prior to the consultation, the Commission drafted a summary that concisely addressed the following themes:

- Organ donation and transplantation in Québec
- The various aspects of organ donation (anonymity, no compensation)
- Donor types (brain dead donors and living donors)
- The issue of consent (explicit, presumed, mandated choice, voluntary registry)
- Recipients (who can be one and how organs are distributed)
- Raising awareness among the population and healthcare professionals
- Other methods to alleviate the organ shortage (donors declared dead by cardiopulmonary arrest, artificial organs, organ commercialization)
- The economic impact of transplant medicine

This consultation paper¹ led the Commission to isolate 33 ethical questions² that served as a basis for its consultation.

The goals of the consultation were as follows:

- Gauge the reaction of the population and people involved in transplantation to the ethical issues raised by organ donation and transplantation and to various current or future strategies to meet the organ shortage
- Determine which values underpin their stances on the issue

Group Interviews

CEST asked the firm Jolicoeur et Associés to conduct group interviews with various stakeholders involved in some capacity in the organ donation and transplantation process. The firm conducted the interviews and produced a summary report (opinions and underlying values).

1. This document (as well as the French version) is available on the Commission website at <http://www.ethique.gouv.qc.ca/eng/ftp/ConsultationDocumentAn.pdf>

2. This document (as well as the French version) is available on the Commission website at <http://www.ethique.gouv.qc.ca/eng/ftp/ConsultationQuestionnementAn.pdf>

Four interviews lasting three hours were held from May 18 to 27, 2004, in Québec City, Montréal (in English and French), and Chicoutimi. As much as possible, participants were seated at three tables:

- A “treatment issues” table, which brought together healthcare professionals (surgeons, emergency physicians, intensivists, nurses or resource nurses, operating room staff, general practitioners, ambulance attendants)
- A “management and organization issues” table, which brought together representatives from Québec-Transplant, foundations working in the field, transplant committees, hospital ethics committees, and hospital administrators
- A “human issues” table, which brought together donors (for living donations) and relatives of donors (for a child or deceased loved one), recipients (those who received an organ from a living person or cadaver), and relatives of recipients (adults or children)

In total, 82 people were interviewed. Before the interviews, each participant received the “Consultation Paper” prepared by the Commission and the related “Ethical Questions” document. However, to streamline groupwork, the questions were pared down to the 12 most important.

Overall interview results³

The following themes came up repeatedly during interviews: the values tied to organ donation are generosity, altruism, and a desire to live on, and those associated with rejecting organ donation are mainly tied to cultural or religious values or certain fears regarding the healthcare system.

- Nothing served to cast doubt on transplant medicine.
- It is important to inform families to encourage donation, but it is also important to respect their loss.
- While criticizing the idea of putting a monetary value on organ donation, participants believed support could nonetheless be given to donors to reimburse expenses incurred by the donation.
- Living donations should stay a personal choice immune to any outside influence
- Opinions were split on the consent models to use, as each model has benefits and drawbacks.
- Brain death criteria were widely accepted. Harvesting protocols seem well established and designed to prevent any hasty harvesting that would be detrimental to dying patient care
- Though selecting donors based on cardiopulmonary arrest criteria was widely accepted for controlled cases, strong reservations were expressed regarding harvesting organs in the event of death by cardiopulmonary arrest for uncontrolled cases.
- Participants thought it important to prioritize those who are most likely to have a successful transplant and who will follow all anti-rejection medication requirements.
- The use of artificial organs did not run counter to the values of consultation participants, but they drew attention to the arduous work involved in developing such organs.

3. The Commission has published its group interview results in *Rapport de consultation sur les enjeux éthiques du don et de la transplantation* and on the Commission website at <http://www.ethique.gouv.qc.ca>.

Online Consultation on the Commission Website

The Commission wanted to experiment with a bilingual (French and English) online consultation for the general population. It was advertised on the Commission website and through calls to local media, information officers in the main healthcare and education networks, and various professional and community organizations. The population was invited to obtain the consultation paper and questionnaire from the Commission Secretariat or consult (and download) them online. The questionnaire could be answered on paper or online and forwarded by mail, by fax, or through the Internet.

The results of this consultation were somewhat disappointing: 35 questionnaires were completed, none in English. The Commission noted that, judging by the answers and several added comments, it was mainly those who had experienced organ donation and transplantation for themselves or loved ones who participated. A few individuals, associations, and organizations also forwarded more detailed comments and answers to the Commission, which included them in its deliberations.

Analyzing the answers shows that participants had not always read the consultation paper before answering the questionnaire and that questions about values seemed to be misinterpreted. Often, only a few questions were answered on the questionnaire, and some answers bore no relation to the question asked. It is therefore virtually impossible to report back in any significant way on the answers obtained. The Commission acknowledges that it played a part in the failure of this consultation, notably due to the questionnaire's length and complexity. It has learned its lesson for future consultations of the same type. However, it remains convinced that an objective questionnaire limited to "True" or "False," or "Yes" or "No"-type questions is of little use in ethical matters and would not meet its needs. A compromise remains to be found.

Mini Phone Survey as Part of the Statmédia Survey in Spring 2004 (Jolicoeur et Associés)

CEST was invited by the firm Jolicoeur et Associés to participate in the spring 2004 Statmédia survey, a phone survey of 1,935 people⁴ from June 16 to July 11, 2004 by Jolicoeur et Associés subsidiary Centre National de Sondage. During this survey, the Commission asked four questions on living donations, financial compensation for cadaveric donations, and consent models. The questions are below, followed by the answer breakdown⁵:

- A) Would you describe yourself as strongly in favor, somewhat in favor, somewhat opposed, or strongly opposed to financially compensating families who consent to donate the organs of a deceased loved one?

Strongly in favor	17%
Somewhat in favor	31%
Somewhat opposed	24%
Strongly opposed	29%

4. The response rate was 48%. Data was weighted so as to match the latest Statistics Canada data on the number of households and the number of those 15 and over in Québec. The margin of error was 2.23% 19 times out of 20, based on a total population of 6,203,100 Quebecers 15 and over.

5. A more thorough study of the survey results, including cross-tabulations needed to interpret the results, is appended to *Rapport de consultation sur les enjeux éthiques du don et de la transplantation d'organes*, available on the Commission website at <http://www.ethique.gouv.qc.ca>.

Support for such a practice is inversely proportional to respondent age and income, with the youngest and low-income respondents being the most in favor of financially compensating families who consent to donate the organs of a deceased loved one.

- B) Would you describe yourself as strongly in favor, somewhat in favor, somewhat opposed, or strongly opposed to the government's creation of a mandatory registry where all citizens must declare whether or not they will donate their organs?

Strongly in favor	38%
Somewhat in favor	29%
Somewhat opposed	15%
Strongly opposed	18%

Support for mandated choice was strongest in the youngest respondents, and francophones supported this consent model and presumed consent equally.

- C) Would you describe yourself as strongly in favor, somewhat in favor, somewhat opposed, or strongly opposed to the idea that all citizens should be presumed to be donors unless they have signed a document to the contrary?

Strongly in favor	30%
Somewhat in favor	25%
Somewhat opposed	18%
Strongly opposed	27%

Allophones are more in favor of presumed consent than the creation of a mandatory registry.

- D) Would you describe yourself as strongly in favor, somewhat in favor, somewhat opposed, or strongly opposed to living donations (e.g., a kidney donation)?

Strongly in favor	50%
Somewhat in favor	41%
Somewhat opposed	6%
Strongly opposed	3%

This support diverges very little by sociodemographic profile.

Appendix 2

Québec Statistics*

Table I
Number of Referrals and Donors

Years	Total number of referrals	Referrals refused	Referrals accepted	Rejected donors	Accepted donors	Living kidney donors
1995	257	124	133	16	117	26
1996	258	121	137	24	113	14
1997	266	152	114	18	96	16
1998	273	129	144	24	120	30
1999	342	193	149	18	131	31
2000	316	158	158	23	135	31
2001	287	128	159	23	136	46
2002	293	139	155	27	127	45
2003	395	216	169	27	142	52

Table II
Number of Patients Awaiting Organs

Years	Kidney	Kidney/ pancreas	Pancreas	Liver	Heart	Heart/ lungs	Lungs	Total
1995	450	8	2	30	27	1	27	514
1996	471	16	5	32	24	1	28	577
1997	498	26	8	42	31	3	29	637
1998	486	37	6	38	29	4	27	627
1999	593	38	15	53	28	3	34	764
2000	637	47	29	46	17	4	35	815
2001	716	57	30	67	31	7	28	936
2002	689	38	28	90	36	4	39	925¹
2003	638	32	18	91 ²	27	6	48	860

1. 1 recipient awaiting an intestine.

2. 4 recipients awaiting a liver-kidney transplant.

Table III
Number of Transplants

Years	Kidney	Kidney/ pancreas	Pancreas	Liver	Heart	Heart/ lungs	Lungs	Kidney (living)	Total
1995	199	2	1	87	51	2	14	26	382
1996	184	1	2	95	37	0	10	14	341
1997	167	1	3	86	44	2	22	16	341
1998	170	3	8	90	36	2	17	30	356
1999	201	7	13	112	39	2	22	31	427
2000	217	3	17	111	44	2	29	31	454
2001	214	6	11	100	39	1	25	46	442
2002	191	8	23	99	43	4	19	45	432
2003	229	3	17	113	47	2	25	52	488

Table IV
Waiting Time (in Days) for Transplant Recipients

Years	Kidney	Kidney/ pancreas	Pancreas	Liver	Heart	Heart/ lungs	Lungs
1995	502	152	318	82	113	148	443
1996	538	36	122	80	84	0	182
1997	474	78	412	90	109	739	426
1998	696	150	331	87	169	166	284
1999	742	734	103	80	223	298	301
2000	653	1,708	640	126	141	104	327
2001	622	434	358	114	137	372	258
2002	709	654	506	125	119	367	478
2003	760	641	231	151	177	894	350

Table V
Number of Deaths While Waiting

Years	Kidney	Kidney/ pancreas	Pancreas	Liver	Heart	Heart/ lungs	Lungs
1995	ND	ND	ND	9	14	2	1
1996	ND	ND	ND	14	11	0	7
1997	ND	ND	ND	10	11	0	8
1998	ND	ND	ND	9	7	1	2
1999	ND	ND	ND	9	12	0	2
2000	23	2	0	13	3	1	8
2001	25	1	1	9	8	0	7
2002	24	0	0	18	12	1	7
2003	12	3	0	12	12	2	5

Table VI
Comparison of 2003 Cadaveric Donor Rates:
Québec, Provinces, and Canada

	Québec	Maritimes	Ontario	Manitoba	Saskatchewan	Alberta	British Columbia	Canada
Population (million)	7,410	2,375	11,874	1,150	1,015	3,064	4,095	31,081
Number of donors	142	36	143	11	19	31	39	421
Cadaveric donor rate per million inhabitants	19.2	15.2	11.8	9.5	18.9	9.9	9.4	13.3

Table VII
Comparison of Cadaveric Donor Rates Per Million of Population (Worldwide)

	1997	1998	1999	2000	2001	2002
Québec	12.9	16.2	17.8	18.3	18.4	17.1
Canada	15.1	14.4	13.8	15.4	13.5	13.1
United States	20.4	21.2	21.3	23.5	21.4	21.5
Spain	29	31.5	33.6	33.9	33.7	33.7
France	15	16.9	16.2	16.2	17.8	20.0
Italy	11.6	12.3	13.7	15.3	17.1	18.1
Great Britain and Ireland	14.5	13.5	13	13.5	15.5	13.0

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