Organ Donation and Transplantation: Ethical Dilemmas Due to Shortage

is the third position statement issued by Commission de l’éthique de la science et de la technologie. The Commission undertook its deliberations with an acknowledgment of the ethical nature of organ donation and transplantation, and has attempted to bring to light the ethical challenges raised by the various strategies, either existing or under consideration, to alleviate the transplant organ shortage.

After summarizing the current state of organ donation and transplantation, the Commission examined the ethical challenges raised by living donations, cadaveric donations—both based on brain death criteria (BDC) and cardiac arrest criteria (non-heart-beating criteria)—consent models for cadaveric donations, broaching the subject with families, transplant candidate selection, and organ distribution. It also looked at the ethical challenges associated with other methods to alleviate the organ shortage, such as organ donation awareness efforts, organ commercialization, xenotransplantation, and the development of artificial organs. The Commission has set out ten recommendations for political and institutional decision maker.

This position statement as well as other documents on the consultations conducted by the Commission as part of its deliberations can be consulted at www.ethique.gouv.qc.ca.

The mission of CEST consists, on one hand, of informing, raising awareness, gathering opinions, fostering reflection, and organizing debates on the ethical issues raised by developments in science and technology and, on the other hand, of proposing general guidelines for stakeholders to refer to in their decision making.
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Monsieur le Ministre,

Je vous transmets par la présente la version finale de l’avis intitulé Le don et la transplantation d’organes : dilemmes éthiques en contexte de pénurie, préparé par la Commission de l’éthique de la science et de la technologie.

Espérant le tout à votre entière satisfaction, je vous prie d’accepter, Monsieur le Ministre, l’expression de ma haute considération.

La présidente,

Hélène P. Tremblay
Sainte-Foy, le 31 octobre 2004

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Madame la Présidente,

Il me fait plaisir de vous remettre l'Avis au ministre du Développement économique et régional et de la Recherche intitulé *Le don et la transplantation d’organes: dilemmes éthiques en contexte de pénurie.*

Je vous prie de recevoir, Madame la Présidente, mes salutations distinguées.

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

[Signature]

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

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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).
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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 factors generally seem to carry the most weight in determining who should be put on

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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 factors 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.

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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.

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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)
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 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)
The ethics of organ donation and transplantation has been the subject of considerable debate and countless publications—to such an extent that organ donation and transplantation are still landmark issues in biomedical ethics today. Transplant medicine adheres to basic principles of bioethics, namely autonomy, beneficence, nonmaleficence, and justice. It also raises issues concerning consent, allocation of limited healthcare resources, quality of life, the relationship between doctors and patients, end of life, and death. As such, transplant medicine exemplifies the inevitable, fundamental conflict between the interests of the individual and those of society.

In spring 2003, Commission de l’éthique de la science et de la technologie (CEST) decided to develop a position statement on organ donation and transplantation. The organ shortage was a main motivation for Commission members. In transplant medicine, the transplantable organs—generally referred to as “solid organs” or “vital organs”—are the heart, lungs, kidneys, pancreas, and liver. It is important to recognize from the outset that the issue of organ transplantation is part of a broader set of issues that also includes tissue transplantation, which raises ethical issues of its own. The use of stem cells to grow organs for transplant is another recent avenue that raises ethical questions. However, these subjects have been excluded from this position statement in order to limit the scope of the work.

With developments in science and technology, transplantation medicine has evolved from an experimental procedure to a routine operation for some patients. Many patients now have a new lease on life. However, the number of organs available for transplant is insufficient. This shortage has led authorities around the world to develop strategies to meet demand for transplant organs. The chief objective of this position statement is thus to address the fundamental ethical issues surrounding organ transplantation, notably as they relate to the primary strategies used to alleviate the organ shortage.

For the first time since it was created in September 2001, the Commission made public consultations a part of its position statement development process. This first experience was positive, but laborious. The results of the consultation are referred to frequently throughout the text. Appendix 1 also provides more information on the various aspects of the consultation.

The first chapter presents a few contextual factors in organ donation and transplantation. After a brief history, the Commission examines the macroeconomic impact of transplant medicine. The Commission considered it important to then show that collective choices for allocating limited healthcare resources have a fundamental ethical dimension. This is followed by a summary of the Québec context and an overview of the stakeholders in the field organ donation and transplantation in Québec. Using the most recent statistics available on the subject, the Commission takes a quick look at the organ shortage and the magnitude of the gap between the number of patients awaiting a transplant and the number of organs available.
The second chapter examines the types of organ donation, including cadaveric donation based on brain death criteria, living donation, and cardiac death criteria donation. The Commission first considers more sensitive issues, such as waiting for brain death, maintaining donors, using separate teams, and protecting donor anonymity. Autonomy and transparency are two values at the heart of the matter. Living donation, which is less widespread in Quebec than in other provinces or the U.S., particularly attracted the Commission’s attention. The Commission explains the complexity of living donation and the risks it entails, looking at issues such as donor and recipient consent, donor evaluation, recipient safety, and fairness toward the donor. It then examines cadaveric donation based on cardiac death criteria. This practice is not current in Quebec or anywhere in Canada, but is gaining popularity in the U.S. and some European countries. However, it raises a number of ethical concerns, which the Commission has considered, including the cessation of life support, criteria for declaring the irreversibility of death, and methods of organ preservation.

Consent for organ donation and the issue of how to approach the family are discussed in the third chapter. The Commission gives an overview of two models of consent (explicit and presumed), as well as two related scenarios (mandated choice and a donor or consent registry). Based on other countries’ experiences, the Commission examines the validity of these models and scenarios and the values they call into play, such as autonomy and solidarity. As for how to approach families about organ donation, the Commission sets out the three essential values that must guide practitioners—respect for families and mourning, information and understanding for families about concepts such as neurological death, for example, and the relationship of trust between healthcare workers and families.

In chapter four, the Commission considers two directly related and extremely complex processes, transplant candidate selection and organ allocation. In considering these two processes, the Commission seeks how best to strike a balance in fairness, effectiveness, and safety. The Commission then describes the process of organ allocation, from harvesting to transplantation, for the various organs transplanted in Quebec.

The fifth chapter takes stock of other means of alleviating the organ shortage, such as public and practitioner awareness, organ commercialization, xenotransplantation*, and artificial organs. Some of these methods raise ethical concerns that were once foreign to the field of transplant medicine, while others raise fundamental questions regarding the distribution of limited healthcare resources. In addition, many values are associated with these various organ shortage strategies. The controversial issue of organ commercialization challenges the values of human dignity, generosity, autonomy, and noncommercialization of the human body.

Despite the complexity of the subject matter addressed in this position statement, the Commission hopes the government will hear its message and note the concerns of those the Commission consulted during its research and consultations. The ethical challenges raised by organ donation and transplantation, as well as social, economic, institutional, and cultural issues they bring into play, are tied to fundamental values in Quebec society: fairness, autonomy, transparency, and safety. But these challenges also have a more concrete component—they affect human beings, including waiting patients and their families, the families of patients pronounced brain dead, workers in the hospital setting, and all Quebecers concerned with collective healthcare choices. With its position statement, the Commission hopes to reach all concerned parties to advance the debate on the ethics of organ donation and transplantation and contribute to ethical decision making.

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1. Terms marked with an asterisk are defined in a glossary in this document.
Chapter 1
Organ donation and transplantation: Some background

Before addressing the ethical issues surrounding organ donation and transplantation in a context of a shortage of organs for transplantation, it is important to understand various facets of the issue. The Commission places the donation and noncommercialization of organs at the heart of its reflective process and, with this statement, endeavors to understand the full complexity of the issue. It also takes a look at the evolution of transplantation as a medical procedure, which reflects the extraordinary progress of science and technology over a relatively short period, itself associated with the shortage of organs in today’s society. The Commission completes its overview of the situation with a look at the current normative context, the economy of the healthcare system, and the various stakeholders responsible for Québec’s encouraging record in the field of organ donation and transplantation.

Theoretical context: Donation

Donation is a very specific phenomenon at the heart of the issues examined in this position statement. As such, the Commission deemed it essential to state its perception of the concept upfront before embarking on the reflective process. It therefore begins with a look at donation in general and organ donation in particular, with a focus on the values that come into play in any position on the ethical acceptability of organ donation: solidarity, altruism, beneficence, generosity, freedom of choice, and integrity of the human body.

The concept of donation

Until recently, the social sciences had paid little heed to the act of donation. But in the last decade or so, especially in France but also elsewhere in the world, a great deal of research has been conducted and much written about the act of donation by philosophers, economists, jurists, sociologists, and anthropologists. Researchers have been interested in understanding what a donation is and how it is addressed in the various social sciences.

From an economic standpoint, in the words of one economist, donation is simply the transfer of an object not covered by a contract. According to Dictionnaire de sociologie, “Law distinguishes the two phenomena (donation and exchange): the right to demand compensation defines exchange but is absent in donation. Giving is therefore to relinquish the right to ask for something in return.”

1. The Commission thanks Jacques T. Godbout, a member of the working committee and co-author of The World of the Gift, for his contribution to this section.
* Unless otherwise indicated, all quotations from French-language sources are our translations.
Although not everything involves donations in society today, people still place considerable importance on goods and services that circulate among them without a contractual obligation to give something in return. Donations are pervasive in significant interpersonal relationships, such as family relationships and friendships. They also play a strong role in goods and services that circulate among strangers, such as humanitarian or philanthropic donations. In Canada, donation is also the underlying principle behind blood collection and organ transplantation.

Definitions of donation emphasize a fundamental characteristic that distinguish it from market exchange: donation guarantees nothing in return. But a nuance must be added here. The lack of obligation to give something in return does not mean there is no benefit to the donor. The lack of intention to get something in return does not mean nothing is actually given. That is one of the most common errors of interpretation. If the giver receives something in return, the easy conclusion is that there was no donation involved. The fact of receiving in return is considered proof that the donation was made for this purpose and that there was no “real” donation, but rather hypocrisy. This reasoning and conclusion are faulty, in that they confuse the fact of receiving in return with the intention to receive. The fact that the donation “gives something back” does not explain the altruistic behavior, in that it is not the motivation. It does not prove the donation was made with this objective in mind. In fact, it proves nothing at all. A parallel can be drawn with a business situation in which someone receives nothing in return simply because of a bad business deal. No one would consider this a donation. It is a logical error to confuse materials that circulate with the meaning they have to the parties involved. In fact, while donating guarantees nothing in return, not only do donors benefit nonetheless, but they often reap a greater return than the donation itself.

First of all, donation is a circulation system with its own set of characteristics distinct from those found in business. It is also distinct from government, which proceeds by collecting tax money and transforming it into services in accordance with the rights of each individual. Donation is not governed by the laws of the market, nor by the usual rules of law and government. Each of these systems of circulation (market exchange, government intervention, and donation) has its own underlying principles—the market is founded on the equivalence of that which circulates, government redistribution is based on equal access and equal rights, and donation is founded on indebtedness. In donation, the parties remain voluntarily in debt to each other. Instead of equivalence or equality, the relationship between the items in circulation is in a permanent state of imbalance.

One of the fundamental characteristics of donation is the freedom the parties enjoy with regard to anything unrelated to their immediate ties. Because donation is not a contract, it is founded on the qualities and characteristics of the relationship between the giver and receiver. In this sense, donating means taking a risk in the relationship, because nothing is “guaranteed” by a third party, as would be the case in a contract.

Donation is nonetheless subject to rules, obligations, and requirements, but the rules are different from those governing other systems. The rules of donation are not those of law or economics. They are the rules agreed upon by the partners, rules arising from the nature, strength, and quality of the relationship between them.

As such, the act of donation is not neutral between the giver and receiver. It affects the relationship, either building and strengthening it or weakening and threatening it, unlike market exchanges, which can be completely anonymous. Thus, there is an obligation on
the receiver in donation, an obligation to receive well. And receiving can be dangerous, more so than in a market system or on account of rights.

In short, the act of donation as the social sciences have come to understand it in recent years is anything but some naive ideal of a free and unilateral gift. Donation is governed by strict rules and supposes a close relationship, which it serves to strengthen. It implies trust between partners, but also helps build and strengthen this trust. When the system works, the benefit to both the giver and receiver is greater than that provided under other systems.

**Organ donation**

How does the general concept of donation apply to organ donation? Are the rules the same? Throughout the process of preparing this statement, the Commission was continually brought back to the importance of the concept of donation and the role it plays in the entire organ transplantation process. It was central to studying the issues of consent, donor and recipient anonymity, living donation, and, of course, organ commercialization.

The Commission recognizes that a donation contains something of donor’s identity, to such an extent that it can even threaten that of the recipient. In the case of organ transplant, for example, patients often experience an identity crisis of sorts due to the nature of the donation. They may want to know more about their donor, so in some way they can keep the organ healthy by treating it as the donor would. For others, receiving an organ from a person who lived differently, perhaps in a way opposed to their values, may be unacceptable. And receiving such a donation—a gift of life—without having the chance to properly thank the donor leaves some people with a feeling of indebtedness that can be difficult to live with.

To begin, the Commission examined the ethical acceptability of organ donation. It saw that the practice was already widespread and well regulated, and raised no objections in society, since everyone is entirely free to donate organs, or to receive them if their health so requires, and that no reciprocation is required. 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 was ethically acceptable.

Altruism, solidarity, and beneficence are values that the Commission believes in, both for individuals and society, and that are fundamental in organ donation. However, it recognizes that these values cannot be universally defined; symbolic representations of life, death, the body, the individual’s place in the universe, and spiritual belief systems underpin values like respect for physical integrity or freedom of choice, which cannot be ignored or dismissed in the context of organ donation. In this sense, the Commission believes that some leeway exists in terms of respect for physical integrity, as long as organs are removed only with the free and informed consent of the donor or family, the priority being the donor’s autonomy and freedom of choice. It should be added that organ removal must be conducted in a manner that respects the body of the deceased and that every effort must be made to minimize and conceal any visible evidence of the procedure.
**Historical context: From miracle to commonplace**

Transplant medicine has advanced in leaps and bounds over the last forty years. As a result of research and experimental surgery and the development of immunosuppressants*, organ transplant “is today considered an effective medical treatment approach for people requiring a transplant, and is no longer a last resort.”

Organ transplants still remain a scientific and technical miracle, but with current success rates, they are no longer the difficult and spectacular event of the past. However, behind this success is a history of scientific hurdles and discoveries.

**Troubled beginnings**

The first scientific work on transplantation was documented in the 19th century. However, it was not until the 20th century that the first animal organ and limb transplants were performed. Dr. Alexis Carrel, a French immigrant to the U.S., began performing this type of experiment as early as 1904. Carrel is considered the founding father of experimental organ transplantation because of his work with vascular techniques. The organ perfusion system* he created with Charles Lindbergh led to the invention of the heart-lung machine by John Gibbon, making open-heart surgery a reality. Although he was unable to prove it, Carrel suspected that cells secreted antibodies* responsible for transplant rejection. He predicted that the effect of leukocytes* would have to be inhibited for the body to tolerate the graft* and reasoned that the spleen and bone marrow produced the antibodies responsible for rejection. Carrel wrote in 1914 that research would have to produce means of inhibiting the organism’s reaction to foreign tissues and adapting the homoplastic graft to the host.

Until then, however, only autografts* were successful, i.e., when the donor and recipient were one and the same. The procedure the Commission has considered in this position statement is allografts, i.e., when the donor and recipient are two separate organisms. In Carrel’s time, allografts and xenografts were much less successful. Because of limited scientific knowledge in this field of medicine, progress from autograft to allograft, then xenograft, was impeded by immunological barriers.

A number of experimental renal xenografts from pigs and monkeys to humans always ran up against the same roadblock—blood would coagulate and obstruct the blood vessels. It seemed that transplantation would, for all intents and purposes, be difficult or even impossible. However, a first great discovery breathed hope into the field of transplant medicine: blood compatibility. In 1900, Viennese researcher Landsteiner discovered the ABO blood group system, which made blood transfusion possible. After many experiments, Mathieu Jaboulay concluded in 1906 that “transplant caused coagulation to occur,” but the organisms were not necessarily incompatible. Paul Ehrlich suggested that rejection was caused by malnutrition of the grafted organ. Following Voronoy’s work with kidneys from cadavers in 1933, hope once again gave way to despair. Even when the donor’s and recipient’s blood were compatible, the Russian surgeon was unsuccessful.

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It was another fifteen years before transplant medicine would make a comeback. Two transplant cases, one in 1947 and the other in 1950, gave researchers new hope. In the first, Dr. David Hume successfully transplanted a kidney into a young woman at Boston’s Bent Brigham Hospital. The woman’s kidney function then returned to normal and the graft was removed. In 1950, this time in Chicago, Richard Lawler transplanted a kidney from a cadaver to a 44-year-old woman. The kidney functioned well and the transplant was successful for six months.

In the early 1950s, two more attempts were made at cadaveric transplant, but the grafts were shortlived. In Paris, Jean Hamburger’s team went so far as to transplant a mother’s kidney into her teenage son, but the organ was rejected some 20 days later. With a single exception, only transplants between twins seemed to last any longer. The scientific community was more and more convinced that tissue incompatibility was the main factor in graft rejection.

Advances in immunology: The key to success

A series of Nobel Prize–winning experiments largely solved the problem of graft rejection. The experiments studied the immune system, the fortress that protects the body from infection and foreign bodies. Jean Desclos declared that “the great, decisive leap in transplant medicine lies in the understanding and control of the immune system.”

Medical advancements in immunology led to the first successful kidney transplant, between identical twins in 1954. Although the notion of antibodies was first broached early in the century by Von Behring, it was not until 1959 that Porter and Edelman were able to define it chemically, and 1978 that Tonewaga was able to explain the genetic makeup of antibodies. It also took many years to develop a solid understanding of the role lymphocytes and macrophages play in the body’s defenses. In the 1940s and 1950s, it was hypothesized that the body rejected grafts for the same reason it fought infections. The most promising avenue seemed to be research into ways of weakening this defense system.

While this research was ongoing, another step forward toward successful organ transplantation was recognition of the similarities and differences between tissue groups. A major contribution to it was Jean Dausset’s work in identifying the HLA system (Human Leukocyte Antigen), “which is the source of the genetic difference and immunological organization of each human being.” With this new understanding in hand, researchers then set out to find a safe way to weaken the recipient's immune system so the body would accept the graft, without putting the patient’s life at risk. But compromising the body’s defenses to make it tolerate a foreign body leaves the recipient vulnerable to other “attacks.”

In the late 1950s and early 1960s appeared the first immunosuppressants (mercaptopurine, methotrexate, azathioprine, steroids). At the time, these products were used alone or in combination to prevent rejection without harming the recipient. Rejection was not yet under perfect control, but the greatest danger for organ recipients

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10. Ibid.
15. S. Sharma and H. Unruh, op. cit.
in the 1960s remained infection. Then in 1972, cyclosporine A, discovered by Jean-François Borel, gave new impetus to the field of transplant medicine. This immunosuppressant, released in 1982, was extremely effective not only in kidney transplants, but also lung, heart, heart-lung block*, pancreas, and liver transplants. A number of immunosuppressant agents have since been brought to market.

The 1960s also saw many improvements and transformations in the field of transplantation. Mechanisms were put in place, primarily in Europe and the U.S., to ensure as perfect a compatibility as possible before performing a transplant. Recipient databases were developed to find the best donor-recipient matches possible. Graft preservation solutions were also developed, and the first transplant using an organ harvested after neurological (brain) death was performed at Massachusetts General Hospital, as opposed to organs harvested after cardiopulmonary arrest, as had been the case previously. Doctors were unanimous—organs taken from donors after neurological death were better quality, because the patient’s cardiopulmonary functions were artificially maintained, keeping the organs supplied with oxygenated blood. But the revolution was as much sociocultural as scientific and technological: our concept of and relationship to death would forever change.

It is certainly too early to draw any definitive conclusions about trends in organ transplant medicine, given its exceedingly short history. The most that can be said is that developments in science and technology have improved transplant surgery.

### Standards context: Standards in place

Written standards on organ donation and transplantation exist at the international, national, and provincial levels. Unlike in most countries, however, Canada (and Québec) has never adopted a law specifically governing the donation and transplantation of organs. Nevertheless, several texts set standards for the practice, although they are not intended to directly govern organ transplantation. The main documents are presented below.

#### Internationally

- The World Health Organization’s *Guiding principles on human organ transplantation*, adopted in 1991. This is a series of nine basic principles covering issues such as organ donation consent, living donation, and organ commercialization.
- The Council of Europe’s *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, also known as the Oviedo Convention (1997). The convention, and especially the additional protocol on the transplantation of human organs and tissues, make an essential contribution to the issue. They address such matters as consent, protection for persons unable to consent, living donation, organ removal from deceased persons, and the commercialization of organs.

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16. Ibid.
In Canada

• The Canadian Charter of Rights and Freedoms, adopted in 1982

• The Criminal Code of Canada, (R.S. 1985, c. C-46), notably sections on homicide and criminal negligence

• Basic Safety Requirements for Human Cells, Tissues and Organs for Transplantation, published in January 2003 by Health Canada. This policy reiterates the importance of complying with certain basic safety requirements for the use and production of human cells, tissues, and organs for transplantation.

• Organ and Tissue Donation and Transplantation, position statement by the Canadian Medical Association. This statement was adopted in 1987 and revised in 2000 to “guide physicians and other healthcare providers, as well as other people responsible for developing policies and protocols on the matter.” This policy statement covers issues such as consent, living donation, determination of death, allocation of organs, and public awareness.

In Québec

• The Québec Charter of Human Rights and Freedoms (R.S.Q., c. C-12), adopted in 1983

• The Civil Code of Quebec (Q.S. 1991, c. 64), notably the following:
  – Art. 3, on the right to personal integrity and inviolability
  – Art. 19, on consent for living donation
  – Art. 24, on written consent and the right of withdrawal
  – Art. 25, on the noncommercialization of organs
  – Art. 43, on consent for donation from deceased persons and withdrawal of consent
  – Art. 44, on family consent for donation from deceased persons
  – Art. 45, on the attestation of death

• The Québec Code of Ethics of Physicians (R.S.Q., c. C-26, a. 87; 2001, c. 78, a. 6)

Economic context: Collective choices for the healthcare system

The economic context of transplant medicine can be analyzed on two levels—one macroeconomic and the other microeconomic. The first encompasses the more general challenge of allocating limited healthcare resources. This is also the level where choices are viewed as more collective in nature—and collective choices and perspectives in healthcare raise major ethical issues, especially in terms of fairness. Fairness refers to access to treatment, equal opportunity, and nondiscrimination. In Québec, these considerations are a matter of collective choice, since the state absorbs the cost of organ transplantation.

It is the Commission’s opinion that any discussion of the economic impact of transplant medicine must be part of a broader analysis of the healthcare system and resource allocation. This report is not intended to question the legitimacy of transplant medicine or attribute it a specific status in the field. In the healthcare hierarchy,
transplantation is not the most costly procedure, nor is the patient pool as large as that for other procedures. However, it is difficult to calculate the actual cost. For example, the figure should include the salaries of healthcare providers with any role in the organ transplant process and the costs associated with intensive care, donor maintenance, surgery, and anti-rejection medication, as well as the cost of recipient’s temporary or permanent withdrawal from the active workforce. The calculation would also be incomplete without accounting for the human cost associated with support for the patient from family and friends. In its Québec action plan on organ donation and transplantation, MSSS recognizes that patients on waiting lists “represent considerable costs for the health and social service network, but these costs are difficult to quantify.”24 However, it is important to remember that some transplants recipients return to the workforce a few months after the procedure, if their health so permits. For example, the cost of renal transplant and five years of follow-up treatment is less than hemodialysis for the same period of time.25

From a macroeconomic perspective, the Commission has identified a number of paradoxes that create friction between fundamental values—autonomy, fairness, and justice on the one side and effectiveness, profitability, and productivity on the other. For example, striking a balance between fairness and effectiveness colors many of the steps in the donation and transplantation process. The Commission considers that efforts should not focus on eliminating these paradoxes, but rather on using the resulting tensions to innovate and seek the balance most conducive to achieving a new understanding of these values.26

In addition, like in the 1991 policy statement on organ transplantation by Conseil d’évaluation des technologies de la santé du Québec (CETSQ), which now goes by the name Agence d’évaluation des technologies et des modes d’intervention en santé (AÉTMIS), the Commission noted a conflict between patient access to transplant medicine and the cost savings of concentrating transplant centers and teams in a few major centers. CETSQ’s stance was that “setting up multiple units across the province would make treatment more accessible to the population.”27 It went on to say that “concentrating multiple procedures in one or two major transplant centers may be preferable based on important considerations”:

1. Functioning and efficiency: possible economies of scale
2. Functioning and effectiveness: the need to maintain a sufficient level of activity at each unit to develop expertise28

According to CETSQ, volume and efficiency were not decisive factors in the cost of organ transplant. CETSQ viewed efficiency as maximizing the use of the resources needed for organ transplantation (equipment, space, specialists, etc.). For example, if a procedure required a specific, costly piece of equipment, it was better to put it to full time use at a few, select centers rather than purchase many of them that would be used only rarely.

25. In Canada, according to A. Laupacis et al., the total five-year cost of renal transplantation is $244,670, versus $400,680 for five years of hemodialysis.
26. The notion of taking advantage of the tensions to innovate is one of the main ideas in a lecture by A. P. Contandriopoulos, “Pourquoi est-il si difficile de faire ce qui est souhaitable ? Quelles idées sur la transformation des systèmes de santé.” Le Managed Care et les NOPS, organized by Département de la santé et de l’action sociale du canton de Vaud, Lausanne, Switzerland, March 24, 1999.
28. Ibid., pp. 49-50.
However, focusing on efficiency could reduce access to the procedure. But, “none of the transplant departments studied herein incurred significant costs for equipment specific to the procedure. […] As such, the economies of scale created by limiting the number of transplant centers to promote high usage would be negligible.”

Volume and effectiveness, the organization explained, were what enabled hospital staff to develop and maintain their transplant skills. The idea is that a minimum number of procedures must be carried out in order to maintain appropriate skill levels. When it prepared its statement, CETSQ did not have sufficient data to determine this number and concluded that there was “no justification […] for insisting that solid organ transplant units perform more than 20 to 25 procedures per year for reasons of efficiency or effectiveness.”

In its action plan, MSSS returned to this concept of “concentration”: “Highly specialized healthcare programs requiring sophisticated technological platforms and rare expertise should be as highly concentrated as possible (seek a critical mass of practitioners and resources).”

That said, fostering fairness means promoting access to treatment without discrimination. As such, equipment and healthcare professionals should be dispersed throughout Quebec to provide access and prevent geographic discrimination. Doing so would, however, be very costly. In contrast, promoting a concentration of equipment and hospital personnel would reduce access and make the process much more complicated for Quebecers living outside major centers. However, it would be less costly and, in theory, more effective. Conflicts of this nature remain a concern, but the Commission considers it important that the approach be to invest in this branch of medicine to promote fairness. In addition, the Commission feels that compromises are necessary to improve access to transplantation, within the constraints of limited healthcare funding.

The Commission would like to draw attention to another paradox: the benefits of promoting the importance of organ donation and a pro-donation culture versus Quebec’s capacity to fund this field of medicine. Collège des médecins du Québec states in its report on potential donors* that “a considerable increase [in the activities of the medical resources directly involved in the field of organ transplantation], considering the surgical procedure and patient follow-up over several years, will have an unquestionable impact on their level of activity and availability.”

As presented by MSSS, the management dilemma raises three issues related directly to the funding of organ donation and transplantation activities:

- The remuneration of physicians involved in organ donation and transplantation poses a certain number of problems.
- The institutions and organizations responsible for coordinating organ and tissue donation are insufficiently funded.
- Québec-Transplant compensation to hospitals for organ donation is insufficient.
Another paradox is also worth noting. Progress in transplant science and technology will surely continue, and even accelerate. New, more powerful and more effective technology is probably on the horizon. At first glance, more effective technology may seem to point to savings, but the Commission believes that once the technology is extended to the entire healthcare network, total costs will be even higher than they are today.

Québec must make decisions on healthcare, and this will continue. As science and technology develop, it becomes necessary to make collective choices that have a real impact on healthcare resources. As such, the Commission feels solutions should be explored that allow transplant medicine to continue to develop without causing an explosion in economic and human costs. The Commission calls on the Government of Québec to examine the issue in collaboration with healthcare professionals and the public.

Québec context: Encouraging performance despite a lack of resources

A vast number and wide variety of stakeholders are involved in organ donation and transplantation. Many hospital practitioners play a role in ensuring the organ donation and transplantation process runs smoothly. Coordinating organizations are also involved along with associations and foundations.

A dynamic field

Before addressing the shortage of organs, the Commission will briefly present the main players in organ donation and transplantation in Québec for an overview of “who does what” in the field. It would also like to stress the commitment they show to the issue.

Organizations, foundations, and associations

In 1992, MSSS made Québec-Transplant responsible for “coordinating and facilitating activities related to the identification, harvesting, and allocation of human organs to foster ongoing improvement in the quality of services for people in need of organ transplants.”35 Québec-Transplant became the primary body responsible for managing the single waiting list for all organ transplants. In addition to this role, Québec-Transplant takes part in many awareness activities, including National Organ Donor Week and various symposiums and conventions.

At another level, a number of charitable organizations are involved in the field of organ donation and transplantation in Québec. The following are a few examples:

• The Canadian Organ Donors Association (CODA) has been working for over 15 years to promote organ donation in Québec. In addition to its awareness activities, it also transports organs for transplantation. CODA works with institutional partners and volunteer police officers from a number of regions of Québec to operate a fleet of vehicles to transport organs and medical teams. Its initiatives include the Nancy-Desharnais eye bank in 1988 and a monument in honor of organ donors in 1994.36 Each year, it organizes an organ donor commemoration event. It also funds purchases of surgical equipment and organ transplant research.

36. From the website of the Canadian Organ Donors Association. [http://www.acdo.ca/en/]
• The **Kidney Foundation of Canada** (which has a Québec branch), is “a national volunteer organization dedicated to improving the health and quality of life of people living with kidney disease.”

As part of its awareness activities in connection with its mission, the Québec branch holds an awareness day during National Organ and Tissue Donation Week, which brings together the main contributors in the organ donation and transplantation community. In addition, the Foundation has been organizing the Professional Forum on Organ and Tissue Donation annually since 2002 in collaboration with Québec-Transplant.

• The **Lina-Cyr Foundation** provides affordable accommodations near Montréal transplant centers for waiting patients, post-surgery patients, and their families. This foundation manages Maison des greffés in Montréal.

Fondation Lina-Cyr recently organized the “Marche des greffés” walkathon to raise funds to build a second facility in Montréal.

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37. From the website of the Kidney Foundation of Canada, Québec branch. [http://reinquebec.ca/fr/index~fr.htm]
38. Ibid.
• Fondation Diane-Hébert was named after the first person in Québec to receive a heart-lung transplant, in 1985. Founded two years later, the foundation helps patients awaiting heart-lung, liver, pancreas, kidney, heart, or lung transplants, as well as other transplantable tissues, such as corneas, skin, bone, joints, and bone marrow.

**Services offered by Fondation Diane-Hébert**

- Patient information and referral to the nearest transplant center
- Moral support with individual and group meetings
- Specialized medical equipment for transplant patients
- Lodging for patients awaiting transplants and patients who have just had their operations
- Awareness activities throughout the province
- A newsletter

Lastly, the Commission recognizes the contribution of other organizations including Association générale des insuffisants rénaux, Association des greffés de l’Est du Québec, the Québec Cystic Fibrosis Association, the Québec Lung Association, the Adult Cystic Fibrosis Committee of Québec, Fondation des greffés pulmonaires, the Heart and Stroke Foundation, and the Canadian Liver Foundation. Committees such as the transplantation committee of Collège des médecins du Québec and the steering committee of MSSS are also worthy of note. These two committees have recently helped develop a better understanding of organ donation and transplantation in Québec.

**Hospital staff**

The hospital and healthcare community is made up of a multitude of professionals involved in organ transplantation, either directly or indirectly. Intensivists, urgentists, respiratory therapists, nurses, and front line practitioners are the healthcare workers most likely to identify potential donors. They are also the ones responsible for keeping the family up-to-date on the patient’s health and usually the ones who request consent for organ donation. Resource nurses trained by Québec-Transplant also play an important role, particularly in supporting families. Intensivists, such as neurologists and neurosurgeons, diagnose neurological death, which is a pivotal stage in organ donation. Medical specialists (nephrologists, cardiologists, hepatologists, pneumologists) evaluate patients who may need organ transplants. In the operating room, surgeons and nurses perform the transplant itself. Social workers, psychologists, and psychiatrists provide pre- and post-operative care. Ambulance attendants are responsible for transporting patients who may become potential donors.

Organ transplant teams work in Québec’s ten transplant centers. Table 1 (next page) lists the types of transplant performed at each center.

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40. From the website of Fondation Diane-Hébert. [http://www.macten.net/fdh/]
41. Collège des médecins du Québec, *op. cit.*
42. Ministère de la Santé et des Services sociaux, *op. cit.*
43. For a more complete account of the role of resource nurses, see chapter 3.
A case of shortage

It has become a cliché to say there is a shortage of organs for transplant. But this very shortage makes certain ethical issues surrounding organ donation and transplantation that much more sensitive. Organ allocation obviously raises ethical issues, even without shortages. However, because of the scarcity of transplant organs, deciding who gets them can be a matter of life or death, making the ethical dilemmas all the more poignant. Other issues such as the acceptance of non-heart-beating donors, the increase in the number of living donors, xenotransplantation, and the development of artificial organs might not be matters of concern in this position statement if it were not for the organ shortage.

Even if enough organs were available for all patients on the waiting list, the number of patients waiting for transplants would not necessarily be less in the future. Currently, organ transplant is indicated when survival or quality of life depend on it. If organs were abundant, however, the list of illnesses treatable by transplant would likely grow longer, thus increasing the number of patients awaiting the procedure. The shortage of organs is a complex problem that cannot be resolved solely by increasing the number of organs available for transplant. Means of controlling demand for organs must be also considered, with a focus on preventing illnesses that can lead to transplant. The Commission also considers it important to bear in mind that the need for organs may rise as the population ages.

### Table 1

#### Organ transplant centers in Québec

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Liver</th>
<th>Lung</th>
<th>Heart</th>
<th>Heart-Lung</th>
<th>Pancreas</th>
<th>Kidney</th>
<th>Kidney-Pancreas</th>
</tr>
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<tbody>
<tr>
<td>Montréal Children’s Hospital</td>
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<tr>
<td>Royal Victoria Hospital (Montréal)</td>
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<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
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<tr>
<td>Saint-Luc Hospital (Montréal)</td>
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<tr>
<td>Notre-Dame Hospital (Montréal)</td>
<td>√</td>
<td>√</td>
<td>√</td>
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<tr>
<td>Saint-Justine Hospital (Montréal)</td>
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<td></td>
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<tr>
<td>Maisonneuve-Rosemont Hospital (Montréal)</td>
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<td></td>
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<tr>
<td>Hôtel-Dieu de Québec (Québec City)</td>
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<td></td>
<td></td>
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<tr>
<td>Centre hospitalier universitaire de Sherbrooke</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Montréal Cardiology Institute</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hôpital Laval (Québec City)</td>
<td>√</td>
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</tr>
</tbody>
</table>

Source: Ministère de la Santé et des Services sociaux

The report by the transplantation committee of Collège des médecins du Québec shows how few cases of brain death occur in Québec hospitals, which is one of the reasons behind the organ shortage. Of the 24,702 deaths in the province in 2000, the committee was able to study the files of 348 potential donors, representing 1.41% of all deaths that year.45

Table 2 on the next page presents organ donation statistics for 2000.

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45. This data does not include potential donors who die in the emergency room. In the study by the College, only patients admitted to the hospital were considered.
A statistical analysis reveals the magnitude of the organ shortage. In 2003, Québec-Transplant received 386 referrals of potential donors, 100 more than in 2002. In 2002, 127 cadaveric donors were accepted, compared to 142 in 2003, providing organs for 488 transplantations. This total includes 52 living kidney donors. Despite these encouraging statistics, 46 people on the waiting list died in 2003. Another 860 patients are still on Québec-Transplant’s waiting list.

Table 2
Statistics on organ donation in 2000

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death in Québec in 2000</td>
<td>24,702</td>
</tr>
<tr>
<td>Potential donors meeting medical exclusion criteria for organ harvesting</td>
<td>8,973</td>
</tr>
<tr>
<td>Donors meeting inclusion criteria</td>
<td>2,067</td>
</tr>
<tr>
<td>Brain deaths</td>
<td>268</td>
</tr>
<tr>
<td>Request made to families of deceased patients</td>
<td>230</td>
</tr>
<tr>
<td>Donors for whom families gave consent</td>
<td>158</td>
</tr>
<tr>
<td>Actual donors</td>
<td>135</td>
</tr>
<tr>
<td>Waiting list in 2000</td>
<td>815</td>
</tr>
</tbody>
</table>

Source: COLLÈGE DES MÉDECINS DU QUÉBEC47.

Québec’s figures for cadaveric donation are excellent compared to the rest of Canada, attesting to its leadership in the field. In terms of the number of donors per million population, Québec is first in Canada (19.2), followed by Saskatchewan (18.9), the Maritimes (15.2) and Ontario (11.8). One notable exception on the international stage is Spain (see inset), with a cadaveric donation rate of 33.8 per million population in 2003. However, Québec’s numbers for living donations are less impressive.

These comparisons all require explanations of the types of organ donation (cadaveric and living). In the following chapter, the Commission will explain the technical aspects of organ donation and related ethical issues.

46. Data from Québec-Transplant; also see Appendix 2 for more detailed tables.
47. Collège des médecins du Québec, Potential Organ Donors in Québec Hospitals, Year 2000, Transplantation Committee Report, April 2003, 30 p.
In terms of cadaveric donation, all eyes are increasingly on Spain. Statistics compiled by Organización Nacional de Trasplantes (ONT), the organization responsible for coordinating organ donation and transplantation in Spain, are impressive. Organ donor rates per million population were 31.5 and 33.8 in 2002 and 2003 respectively. Compared to rates in other countries, such as the United States (22.1), Great Britain (12.1), or France (18.3), Spain is clearly in a class of its own.

There are a number of factors behind Spain’s success. First, the country introduced a national strategy to stem the decline in the number of organ donors. It began by remedying three main problems: poorly trained organ donation teams, unidentified potential donors, and the qualms of healthcare professionals about broaching the issue with families. To correct the situation, in 1989 the health department set up ONT, an independent agency made up of hospital health professionals and managers. ONT has since developed a system coordinating all aspects of organ donation and transplantation at the national, regional, and local levels.

Each hospital has an organ donation coordinator—usually a nephrologist or intensivist—responsible for recruiting potential donors. The coordinator also keeps an eye on the hospital’s death registry to ensure potential donors are not overlooked and takes part in developing organ donation policies at the regional and national level. ONT has made coordinators, hospitals, and regional healthcare authorities accountable for their cadaveric donation rates by implementing a system of indirect incentives for hospitals and making their rates public.

Awareness has also been raised among hospital professionals through special training by the Spanish Organ Donor Service, as well as among the media through periodic conferences on organ donation, all to build a more donor-friendly culture through a better-informed population. Lastly, a 24 hour hotline was put in place for access to the latest news on organ donation.

Also important is the fact that in Spain, all patients are considered potential donors unless consent has been explicitly refused (presumed consent). Physicians do, however, ask the family of the deceased for authorization to harvest organs. The family refusal rate is declining in Spain, while it has remained stable in other countries.

However, the Spanish rates must be put into perspective relative to those of other societies. The statistics for Spain reflect the number of potential donors, not the number of actual donors. Spain also frequently accepts older donors in the 45–60 age group, and even 60 and over, which is less common in other countries. This approach expands the donor pool, but perhaps at the expense of transplant quality. Many experts also question the use of donor rates per million population. The criticism is that the statistics do not reflect the total number of deaths, and even less so the number of deaths per category of potential donors. This leads many people to believe Canada will never achieve the Spanish rates, for the simple reason that its demographic pyramid is different and its death rates are not comparable.

As a whole, while Spain’s figures are extremely high for potential cadaveric donors, its living donor rate is much lower. The Canadian rate for 2003 was 12.7 pmp (and 4.8 pmp in Québec), versus only 1.4 pmp in Spain.

52. Ibid., p. 501-512.
53. D. Baxter, Beyond Comparison: Canada’s Organ Donation Rates in an International Context, The Urban Futures Institute Report 51, Vancouver, 2001, pp. 5-
54. Ibid., p. 19.
Chapter 2
Organ donation: Technical aspects and ethical issues

Organ transplantation is a field of medicine that, like many others, is constantly evolving. As discoveries have been made and research conducted, organ donation has taken many forms, endlessly raising ethical questions. Organs can be donated at death (cadaveric donation) or in life (living or inter vivos donation). For cadaveric donation, we must be certain that the donor is really dead, which raises the whole issue of criteria for the determination of death. For living donation, the Commission has focused on the ethical concerns of consent, evaluation, donor and recipient safety, and fairness to donors.

The current situation: Cadaveric and living donation

Today, organs can be donated after a diagnosis of brain death or while the donor is still alive. The Commission will first examine these two types of donation to provide an overview of the ethical issues they raise.

Cadaveric donation based on brain death criteria (BDC):
A well-established practice

Not long ago, patients were considered dead when their hearts stopped beating and they stopped breathing. However, with the development of new resuscitation techniques, some patients are now irreversibly unconscious, in deep coma, and completely dependent on a ventilator. Research in the 1950s and 1960s culminated with the publication of a report by the Ad Hoc Committee of the Harvard Medical School establishing brain death criteria. The primary objective of the report was to define brain death, now also known as neurological death. Since the 1970s, this has been the new basis for pronouncing death. These new death criteria were added to the traditional criteria, i.e., the cessation of cardiopulmonary functions.

Patients pronounced neurologically dead are the best candidates for organ donation, because while they are and have been pronounced dead, their heart and respiratory functions can be artificially maintained to keep their organs supplied with oxygenated blood. This keeps them in good condition until they can be removed.

However, much remains to be done to make healthcare workers more aware of brain death and how to test for it. Debate also still continues on the validity of the brain death criteria in use, notably from an ethical standpoint, although the criteria are accepted in nearly all Western countries. Moreover, the notion of brain death calls into question various concepts of death and the human body derived from certain popular and religious

1. Synonym of brain death
2. See chapter 5
beliefs or philosophical convictions. Problems can therefore arise when approaching families about organ donation after neurological death. Because the heartbeat and breathing are artificially maintained, families may have the impression that the patient is still alive.

In April 2003, the Canadian Council for Donation and Transplantation (CCDT) acknowledged the need for criteria accepted at the national level (see inset). After the Canadian Congress Committee on Brain Death in 1988 and the Canadian Neurocritical Care Group in 1999, CCDT formulated “minimum standards.” These standards are to “serve as a framework for developing regional or local guidelines and provide the opportunity to play a leading role at the international level.”

The organ donation process: Who becomes a donor?

From identification of a potential donor to harvesting of the organs, the process is very rapid, but entails many steps and actions by hospital health workers. The steps can be very technical, such as blood tests, but also very emotional, like raising the issue with the family. The following is an explanation of the organ donation process in an ideal situation.

The first stage is to identify patients presenting signs of possible neurological death in the short or medium term. Support is provided to the family, and the resource nurse is informed of the potential donor. The potential donor is reported to Québec-Transplant. Physicians must then determine whether the patient is approaching brain death. Failure to identify cases of neurological death has an impact on the total number of donors, and each unidentified potential donor represents multiple organs that will never be transplanted. If the patient is pronounced brain dead, the physician explains the diagnosis to the family.

Two authorizations may be required before the donor is assessed: one from the family and the other from the coroner, if applicable. A coroner’s authorization is required if there is any doubt as to the circumstances surrounding the death that could make an autopsy necessary. Otherwise, the family’s consent is sufficient. The medical team can then evaluate the donor. This step is necessary to determine whether the organs are viable for transplant and establish the absence of any exclusion criteria. The appropriate medical tests are performed. When death is pronounced and throughout the process that follows, the donor must be maintained to preserve the quality of the organs. It is important to stabilize and maintain the potential donor to keep the cardiopulmonary functions active and the transplant organs oxygenated. The donor can then be transported to an organ donor center, where the organs can be harvested.

4. For example, the concept of brain death has recently been accepted in Japan after a long process, but the country is not unanimously in favor. For more information on the subject, see M. Lock, Twice Dead. Organ Transplants and the Reinvention of Death. Los Angeles, University of California Press, 2002. 429 p.
6. The issue of approaching the family and the ethical questions it raises are more thoroughly examined in chapter 3.
The issue of support: Awaiting brain death

After severe trauma, some patients may decline very slowly toward neurological death. They will never regain consciousness, and medical care is for comfort only. Sometimes families may prefer not to prolong this type of wait and ask that life-sustaining treatment be withdrawn, and sometimes patients themselves may have earlier stated they did not want life-prolonging treatment. These patients never meet the criteria for neurological death. And, since neurological death is a prerequisite to all potential organ donation, their organs cannot be harvested.

Maintaining the life of patients declining toward brain death entails harrowing decisions in terms of resource allocation, particularly for intensivists. This type of care consumes considerable human, material, and financial resources, but can result in more organ donations.

The issue of transparency: Separating teams

Collège des médecins du Québec is uncomfortable with the fact that “the attending physician pronounces brain death and maintains the donor until the organs are removed.” In the opinion of CMQ, in the interests of greater transparency, the attending physician should treat the patient only until death is declared, and the maintenance of hemodynamic functions* should be handed over to a second team. Because of insufficient medical staffing, it would not currently appear realistic to have a second team take over care of the potential donor upon the determination of brain death. While it agrees with CMQ and despite the possible breach of transparency, the Commission is of the opinion that if an experienced medical team is not available when a patient is pronounced dead, it is the attending physician’s duty to maintain the donor’s functions until the organs are removed. The Commission considers this the best procedure under the current circumstances.

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An issue often raised during the Commission’s consultations was people’s fear they would not receive the care they needed if they were recognized as organ donors. Some people fear if they are identified as having consented to organ donation, every effort will not be made to save their lives, and the focus will instead be placed on organ donation. However, article 45 of the Civil Code protects patients from any premature diagnosis of brain death. It requires that the team responsible for declaring death and whose primary concern is ensuring patients receive the care their condition requires be separate and distinct from the team responsible for harvesting the organs. Article 45 states that “no part of the body may be removed before the death of the donor is attested by two physicians who do not participate either in the removal or in the transplantation.” In addition, it would be against medical ethics to prematurely pronounce a patient dead for the purpose of organ donation. Lastly, because of logistic limitations, the pronouncement of death and the removal of organs usually take place at two different hospitals.

The Commission considers it crucial to maintain the separation of the medical teams responsible for pronouncing death and removing organs. The Commission believes this will preserve the necessary transparency and reassure the public.

The issue of anonymity: Maximizing benefits and minimizing risks

In some cases, donors’ and recipients’ families feel the need to talk. Families are motivated primarily by the desire to see the good that came from their loved one’s death and confirm that the organs were in fact donated and transplanted. It is important to note that some families are hesitant to consent to donation due to a lack of trust in the transplant system. As for recipients, contact with donor families is an opportunity to thank the people who saved their lives or helped them greatly improve their quality of life.

For the time being, the donor and recipient are kept anonymous so that neither one knows the other’s identity. They can communicate anonymously in a letter, which is forwarded by a third party (e.g., Québec-Transplant or the attending physician).

Communication between the people involved is usually mutually beneficial, and the risk of complications is generally avoided. However, letters exchanged between donor families and recipients can at times lead to inappropriate requests or remarks. For example, families may ask of recipients that they act in a very specific way to perpetuate the behavior or personality of the donor through the organ. Likewise, recipients may ask for personal information about their donors that families do not wish to share—or even for financial support. In the opinion of the Commission, such requests are out of line and must be prevented. The Commission considers it essential to protect the gratuitous nature of donation, prevent any attempt to extort property or money, prevent harassment in any form, and protect the right to privacy.

Given the importance of receiving something in return in the donation process, the Commission does not wish to close the door to the possibility of consenting adults (recipients and donor families) coming together to express their appreciation and offer encouragement. It would be overcautious and inappropriately overcontrolling to prevent these meetings on account of a few unacceptable situations that have occurred in the past. However, it would appear best for the parties to allow a certain period of time to pass in order to let things settle so they can think clearly about any potential meeting.

Recommendation No. 1

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

Living donation

The kidneys, lungs, and liver are all considered vital organs. It may not be immediately obvious that they can be donated as full or partial organs by living donors, which is both possible and fully legal in Canada, including Québec. Living donation is also possible for the kidneys and a single lobe of the liver or lungs. Astonishingly, heart transplantation is also possible from living donors. This is known as a “domino” transplant. In some cases, it can be better for a patient awaiting a lung transplant to receive a heart-lung transplant. The patient then donates his or her own heart to receive the combination transplant. The heart can then be transplanted to a patient waiting for a heart.

In general, people donate a kidney or partial organ to kin (genetic bond) or a loved one such as a spouse or a friend (emotional bond). Sometimes, but more rarely, people express the wish to donate an organ without designating a recipient, as a “good Samaritan.” This has long been practiced for blood or sperm donation, and is increasingly common for bone marrow. In some countries, such as India and Great Britain, living donation from nonrelatives is prohibited, with a few, rare exceptions. The purpose is notably to reduce the risk of financial compensation to the donor.

In 2003, 52 of the 281 kidney donations in Québec were from living donors, for 18.5%. Québec’s living donor rate per million population (6.1) is below the Canadian average (13.9). In the U.S., the living kidney donation rate has been higher than cadaveric kidney donation since 2001. Indeed, living donation is considered a strategy that could at least partially alleviate the organ shortage. This option was firmly supported by respondents to a survey conducted for the Commission in spring 2004, as well as by participants in the Commission’s group discussions and online consultations.

From a legal standpoint, the Civil Code regulates living donation, i.e., donation from living donors. It states that “a person of full age who is capable of giving his consent may alienate a part of his body inter vivos, provided the risk incurred is not disproportionate to the benefit that may reasonably be anticipated.” The donor must also give written consent. A minor or a person of full age considered incapable of giving consent may “alienate a part of his body only if that part is capable of regeneration and provided that

9. In the U.S., partial intestinal grafts are also possible.
12. Ibid.
13. Ibid.
14. 91% of respondents to the omnibus survey conducted for the Commission in spring 2004 said they were in favor or somewhat in favor of living donation. See Appendix 1 for a summary of the results of the Commission’s mini-survey.
no serious risk to his health results.”16 Minors and persons of full age considered incapable of giving consent are therefore prohibited from donating organs, because the body parts in question are not capable of regeneration.*

From an ethical standpoint, living donation is quite a peculiarity, since it defies the general rule that all organ donors must be pronounced dead before organs are removed (dead donor rule). This type of exception can only be justified in certain conditions, such as the potential of saving a loved one’s life at a time of organ shortage. It is in this spirit that the Commission supports living donation, either from family members or other donors.

**A contravention of the “do no harm” principle**

Living donation brings into play the “do no harm” principle. This principle states that “the potential harm to the other party, even with the person’s individual consent, imposes a *prima facie* obligation to ensure that the benefits outweigh the harm.”17 In short, before removing an organ or part of an organ, it must be established that the benefit to the donor is greater than the damage of the procedure. The removal of an organ or part of an organ from a healthy person could potentially (but not necessarily) affect his or her quality of life immediately or in the longer term. The procedure may therefore seem unjustifiable, as a mutilation with no physiological benefit to the donor. However, the psychological benefits can be great.

Gutmann and Land introduced an interesting concept for weighing the costs and benefits of living organ donation. In their opinion, the calculation must take into account not only the benefits to the recipients, but also those to the donor.18 This concept was expanded on in the Consensus Statement on the Live Organ Donor, published in the U.S.19 The benefit to the donor is psychological: saving the life of kin, a child, a spouse, or a friend or significantly improving the quality of life of a loved one is a considerable—and even vital—benefit to the donor. Although the donor may feel a certain pressure to donate,20 the Commission’s consultation showed that helping a critically ill loved one is unquestionably a powerful motivator for donors. To compensate for the risks to the donor, a U.S. task force recently suggested giving living donors priority if ever they themselves need an organ transplant.21

**The issue of anonymity**

With the exception of special, rare “good Samaritan” cases, living donor anonymity cannot be preserved. It is impossible to conceal the recipient’s identity from the donor, and vice versa, when the parties have family or emotional ties. This lack of anonymity raises a number of ethical issues, especially with regard to freedom of consent. For example, people are always free to consent to donating or refuse to donate a kidney or part of an organ, but if the recipient is related genetically or emotionally, the potential donor may feel tremendous pressure to donate, reducing the autonomy essential to freedom of consent.

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20. For example, it is easy to conceive that a parent would feel an obligation to help a child in need of a transplant
According to the professionals consulted by the Commission, medical teams always wait until an individual volunteers to make a living donation of an organ to a family member in need. Physicians do not pressure the patient’s family or friends to donate. The Commission considers this practice instrumental in preserving the spontaneous, generous nature of donation and promoting freedom of consent. Still, the relationship between the donor and recipient can have an impact on the donor’s freedom of choice. Genetic or emotional ties between the donor and recipient inevitably lessen donor autonomy by appealing to family duty. This concern was raised during the Commission’s consultation.

In a brief on December 20, 1999, on organ and tissue removal, Belgium’s Advisory Committee on Bioethics stated that—

> This duty of solidarity holds that individuals exist physically, but especially psychologically, culturally, and economically, only in terms of their relationship to other humans. This is not just a childhood phenomenon, but a lifelong relational reality. It is the foundation of ethical values themselves; the human dignity of each individual derives from the fact that it is recognized by society and each of its members. Paradoxically, even individual autonomy requires the consensus of all. Solidarity as a value therefore reflects recognition of each individual’s “debt of assistance” toward all others.

Each individual, in the course of personal growth, assumes the autonomy learned from others. It becomes an essential part of the individual’s physical and psychic identity and dignity. At times, the value of solidarity can conflict with that of autonomy. It is generally agreed that nobody should be forced to sacrifice their health, and especially their life, for the sake of solidarity toward another.22

Nevertheless, the Commission deems that this conflict between autonomy and solidarity does not justify prohibiting living donation. Donor autonomy can be protected by means such as providing donors with all relevant information on the potential risks and benefits and allowing them to withdraw consent confidentially at the time of evaluation. The issue of evaluation is addressed later in this chapter.

The Commission considers it critical that living donors be duly informed of the risks to their physical and mental health. In accordance with the conditions of free and informed consent and the Council of Europe’s Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, the Commission deems that all living donors should ideally be informed of “the right to have access to independent advice about such risks by a health professional having appropriate experience and who is not involved in the organ or tissue removal or subsequent transplantation procedures.”23 But the Commission acknowledges that, in real terms, this measure would be difficult to enforce in Québec, where health professionals with “appropriate experience” are usually involved in the organ transplantation procedure and cannot serve as independent advisors.


In the U.S., recommendations have been made on ensuring the consent of live donors is free and informed. According to the Advisory Committee on Organ Transplantation (ACOT) of the Department of Health and Human Services (DHHS), the donor must be—

- Competent (possessing decision making capacity)
- Willing to donate
- Free from coercion
- Medically and psychosocially suitable
- Fully informed of the risks and benefits as a donor
- Fully informed of the risks, benefits, and alternative treatment available to the recipient

ACOT also endorses the following two principles:

- Equipoise; i.e., the benefits to both the donor and the recipient must outweigh the risks associated with the donation and transplantation of the live donor organ
- A clear statement that the potential donor’s participation must be completely voluntary, and may be withdrawn at any time

Despite all these principles and rules governing consent for living donation, it is difficult to assess the living donor’s real motivation and the authenticity of the gesture. The degree of motivation reflects the real desire to donate an organ. It also must be determined whether donors are acting in full autonomy or are under pressure from family or friends. Authenticity refers to the gratuitous nature of the donation, i.e., the donor does not expect anything in return for the donation and no such promise has been made. These two criteria are measured, along with more technical criteria such as donor-recipient compatibility, at the time of donor evaluation.

As for the recipient, it is difficult to establish to what extent a patient waiting for a transplant can refuse a donation from a living person. Potential recipients could be placed at risk of blackmail by a potential donor demanding something in return. Psychological assessment is intended to reveal any such likelihood, but the Commission is fully aware of the difficulty of doing so. The Commission considers it sufficient reason to reject an offer of living donation if any intention is detected or confirmed to ask the recipient or family to compensate the donor.

The issue of donation authenticity: Evaluating donors

Transplant centers require that anyone expressing a desire to make a living donation undergo a physiological and psychological evaluation. The ultimate objective of the evaluation is to establish whether the benefits expected by the donor and recipient outweigh the anticipated risks. It is also a means of ensuring the validity of the process leading to the donor’s consent.

First, the physiological compatibility of the donor and recipient must be established. If the match is positive, the evaluation process can then continue. The next step is to identify any factors that place the potential donor at too high a risk or any contraindications to the organ removal or transplantation. Recent deaths of living donors have refueled fears about

25. The issues of living donor compensation and organ trafficking are addressed in more detail in chapter 5.
Chapter 2—Organ donation: Technical aspects and ethical issues

The issue of safety: Transplanting quality organs

For kidneys, living donor transplants are more successful than cadaveric transplants, both in terms of patient survival and graft survival. It hence appears as safe, if not safer, to graft an organ or partial organ from a living donor than from a cadaveric donor. In this respect, Belgium’s Advisory Committee on Bioethics states that—

Immunological analyses of both the recipient and donor (determination of both erythrocyte and leukocyte blood groups) can be performed more thoroughly, since the situation is not as urgent as in the case of a donor pronounced brain dead. Factors contributing to the short and long term superiority of renal transplants from living donors compared to cadaveric donors include recipient preparation, transplant kidney quality assessment, the absence of the organ distress often encountered with cadaveric kidneys, better identification of transplant antigens (HLA), and the extremely short interval between removal and transplantation […].

27. U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation, op. cit.
28. According to the few studies on living donors of kidneys or liver or lung lobes, the donor mortality rate appears very low, and even nil in some studies. Living donors’ post-donation quality of life is comparable to before the donation.
30. For example, this feeling of obligation can be particularly strong for the mother or father of the recipient.
31. Comité Consultatif de Bioéthique, op. cit.
As for the liver and lungs, the experts and research consulted\textsuperscript{32} by the Commission report good results from lobe grafts. However, sufficiently extensive studies are not available to compare these results with transplants from cadaveric donors. \textbf{In this respect, the Commission deems that research should be conducted to compare the results of liver or lung lobe transplantation from living donors and cadaveric donors.}

\textbf{Recommendation No. 2:}

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

\textbf{The issue of fairness}

For the donor, living organ donation entails hospitalization that varies in length. In the past, donors have faced discrimination from their employers, for example, due to missed work days. \textbf{In the spirit of the Jurors Act,\textsuperscript{33} the Commission considers it unacceptable for an employer to dismiss, suspend, or transfer an employee or discriminate, take reprisals, or penalize the employee in any way for donating an organ.} To the Commission, making a living organ donation is a generous act that demands fair treatment of the donor.

Throughout this position statement, the Commission emphasizes the gratuitous nature of organ donation as an altruistic gesture. As a general rule, living donors must assume certain costs, notably for accommodation and travel, that are currently not reimbursed. Given that such a reimbursement would in no way be a source of profit to the donor, the Commission considers it unrelated to the issue of organ commercialization.\textsuperscript{34} The question is therefore whether it is acceptable to reimburse these expenses and whether this would detract from the generous nature of the act.

The Commission believes that reimbursing living donors for the expenses incurred is a matter of fairness. \textbf{The Commission considers it inappropriate to ask donors to personally shoulder expenses they must incur to make this extraordinary gift.} The organ donation and transplantation professionals consulted by the Commission are virtually unanimous—the expenses incurred by donors and their families for travel, medication, and accommodation near an organ removal center should all be reimbursed. As such, the Commission makes the following recommendation.

\textbf{Recommendation No. 3:}

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

\textsuperscript{32} For the liver, see O. Retry et al., “Living Related Liver Transplantation in Adults: First Year Experience at the University of Liège,” \textit{Acta Chirurgica Belgica}, Vol. 104, No. 2, April 2004.

\textsuperscript{33} \textit{Jurors Act} (R.S.Q., chapter J-2, 2001, c. 26, art. 131).

\textsuperscript{34} See chapter 5
An avenue to be explored cautiously: donation after cardiac death or based on cardiac death criteria (CDC)\textsuperscript{35}

Due to the growing gap between the number of organs available and the number of patients awaiting them, additional avenues of expanding the donor pool must be explored. One way of achieving this would be to include another type of cadaveric donor based on cardiac death criteria (CDC). The U.S.,\textsuperscript{36} Europe,\textsuperscript{37} and Japan have protocols in place for this type of organ donation. Given the growing use of CDC abroad, the Commission felt it was important to reflect on the issue. However, the Commission deemed it inappropriate to consider a further possible category of organ donors: patients in a persistent vegetative state. Their inclusion would require redefining the criteria for the determination of death, which is beyond the scope of this position statement.

Every year, a number of patients die in hospitals following serious brain injury without meeting the technical criteria for brain death. Their survival depends on life-sustaining treatment. However, if the family and physician agree to end treatment, artificial life support is discontinued and the patient dies minutes or hours later. Death is then declared using cardiopulmonary criteria.

There are two general categories of cardiac death potential donors: controlled and uncontrolled. The first category refers to donors whose life-sustaining treatment is terminated in a hospital setting. The second refers to donors whose cardiopulmonary arrest is unplanned (see Table 3).

Under the Maastricht classification (see inset), cardiac death patients are grouped into four subcategories, of which three (I, II, and IV) are uncontrolled. The first category includes patients whose hearts stop beating before they arrive at the hospital. The second category is made up of patients whose hearts stop beating at the hospital and who cannot be resuscitated. The fourth category consists of patients whose hearts stop beating spontaneously after brain death.

**Controlled cardiac death patients** make up category III. This group includes patients admitted to critical care units who are either conscious (but with minimal quality of life) or unconscious (but not brain dead), and whose chance of survival in the short or medium term is negligible.

Organs can be harvested from this type of donor after the declaration of cardiopulmonary arrest, and therefore death. The dead donor rule is thereby respected.

\textsuperscript{35} Synonym of “non-heart-beating donors (NHBD)”
However, organ removal from cardiac death patients raises ethical concerns, including the withdrawal of life-sustaining treatment, the irreversibility of death, and organ preservation.

### Maastricht classification for cardiac death patients\(^{38}\)

- Brought in dead
- Unsuccessful resuscitation
- Awaiting cardiac arrest
- Cardiac arrest after brain-stem death

### Table 3

**CDC organ retrieval algorithm**

<table>
<thead>
<tr>
<th>Cardiac death criteria donor</th>
<th>Controlled</th>
<th>Category III</th>
<th>Uncontrolled</th>
<th>Categories I, II, IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Termination of life-sustaining treatment</td>
<td>Cardiopulmonary arrest</td>
<td>&gt; 1 hour</td>
<td>No retrieval</td>
<td>Irreversibility interval (2-5-10 minutes)</td>
</tr>
<tr>
<td></td>
<td>Cardiopulmonary arrest</td>
<td>&lt; 1 hour</td>
<td>Organ preservation</td>
<td>Retrieval</td>
</tr>
</tbody>
</table>

Source: COMMISSION DE L’ÉTHIQUE DE LA SCIENCE ET DE LA TECHNOLOGIE.

**Stopping life-sustaining treatment**

The relationship between the termination of life-sustaining treatment and transplant medicine is delicate and calls for particular attention. The risk of complications and abuse is great and health workers’ fears are real, as the Commission observed. Since death is the unconditional prerequisite to cadaveric organ donation, some people fear life-sustaining treatment will be more readily withdrawn or end-of-life palliative care neglected in order to more quickly treat patients waiting for organ transplants. This fear is, however, unfounded in Québec hospitals, where checks and balances are already in place to prevent potential abuse. Nevertheless, the Commission has taken a look at the issues of consent, transparency, and safety in an attempt to identify the potential risks.

**The issue of consent**

The issue of consent takes on a whole new dimension when it comes to CDC donors. In (rare) cases when the patient is conscious, approaching the patient about organ donation is obviously very delicate. For example, patients still undecided about terminating life support may feel undue pressure to cease treatment if healthcare workers have already raised the issue of organ donation. On the other hand, some patients may express the wish to donate organs of their own accord. Consent given in this way is an extremely valuable testimony, since it comes directly from the patient.

For patients who are unconscious, families are the ones who must give their consent rather than the patients themselves. From discussions between the Commission’s working committee and health workers, it was clear that the people responsible for approaching the family must explain the irreversibility of the patient’s condition, the technical aspects of organ preservation (e.g., insertion of a cannula* to perfuse the organs), the family’s presence at the patient’s bedside when life-sustaining treatment is withdrawn, the various scenarios, and the steps to be taken as the situation progresses. The stakeholders consulted also drew attention to problems in obtaining family consent, notably for terminating life-sustaining treatment, and the issue of consent when the family cannot be contacted or informed in advance. In this respect, the Commission makes the following recommendation.

**Recommendation No. 4:**

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 family only after the decision to stop life-sustaining treatments has been made and confirmed.

In Canada, the families of patients who could be considered potential CDC donors and have suffered brain injury can currently choose to wait until it is determined whether the patient’s condition will lead to brain death. Because this wait can be long and arduous, families usually choose to withdraw life support treatment, and the patient dies without organs being harvested.
The issue of transparency

Some experts have pointed to the possibility of a conflict of interest among healthcare workers responsible for terminating life-sustaining treatment and retrieving organs.39 The conflict lies between two separate duties of healthcare professionals—to provide patient care and pain relief and to help potential organ recipients. Although patient wellbeing is central to both, healthcare professionals are placed in a delicate situation in which the death of one patient can be beneficial to another. As such, a consensus is emerging on the separation of the medical teams responsible, on the one hand, for patient care, the termination of life-sustaining treatment, and the pronouncement of death, and, on the other hand, organ retrieval.40 This separation of responsibilities is facilitated if organ retrieval does not take place at the same hospital as declaration of death. In the case of CDC, due to logistical and organ viability considerations, these two functions must be performed at the same facility, increasing the risk of conflict of interest. While the organ retrieval team awaits surgery, another team terminates the patient’s life-sustaining treatment and declares death.

The Commission deems that, to ensure the full transparency required, the teams responsible for, on the one hand, patient care, the termination of life-sustaining treatment, and the determination of death, and, on the other hand, organ retrieval must be independent.

The issue of safety

Once life-sustaining treatment is terminated, the medical team must wait for cardiopulmonary arrest before declaring death. The interval may extend beyond a certain threshold considered critical for organ viability. Most U.S. protocols set the maximum interval before cardiopulmonary arrest at one hour.41 Beyond this limit, the patient’s organs are no longer considered viable for transplantation. In fact, the moment life support treatment is withdrawn, organ quality begins deteriorating as blood circulation slows and organ oxygenation declines.

In some countries, protocols allow for cardiac resuscitation of the donor after death is pronounced in order to minimize the warm ischemic time*, i.e., the time during which the heart no longer circulates oxygenated blood.42 Rapid organ deterioration is also the reason some organs are less likely to be harvested from CDC donors. The kidney currently remains the organ most often harvested from this type of donor, although some centers also report liver, pancreas, and lung transplantation.43 Given this, it comes as no surprise that few transplant centers perform uncontrolled CDC organ retrievals, since the warm ischemic time is rarely known. In the absence of this vital information, it is virtually impossible to assess organ viability.

A number of studies have compared organ quality and the impact on recipients depending on whether the organs come from cadaveric donors based on non-heart-beating death or brain death criteria. For cadaveric donors based on brain death criteria (BDC), cardiopulmonary functions are maintained with specialized equipment, keeping the organs supplied with oxygenated blood. In general, research has shown that organ quality is more or less equivalent for the two types of donors. However, at least for renal transplants, cardiac death organ transplants are less successful in the short term. In the medium term, on the other hand, the survival rates are comparable. Still, the professionals consulted by the Commission expressed concern as to the quality of organs from cardiac death donors.

The irreversibility of death: In search of consensus

Once life-sustaining treatment is withdrawn, cardiopulmonary functions usually shut down within a few minutes or hours. According to the protocols currently in use, if cardiac arrest occurs within an hour of treatment cessation, a specific length of time must elapse before the patient can be pronounced dead. However, there are disagreements as to the appropriate length of time, as illustrates the range of intervals recommended by the various protocols.

### Various intervals between cardiac arrest and determination of death

- **Maastricht Protocol:** in 1995, 10 minutes
- **Institute of Medicine:** in 1997, 5 minutes; in 2000, no consensus
- **Health Council of the Netherlands:** in 2003, 5 minutes
- **Pittsburgh Protocol:** in 1999, 2 minutes
- **Society of Critical Care Medicine:** in 2001, minimum of 2 minutes, maximum of 5 minutes

The U.S. Institute of Medicine, in its report on cardiac death donation emphasized the need for studies on cardiac arrest patients in order to develop a consensus on the appropriate interval for physicians to respect between cardiopulmonary failure and the pronouncement of death. Some stakeholders also raised concerns about setting an interval without the backing of scientific research.

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It is universally accepted in the medical community that a patient whose heart stops beating and lungs cease functioning cannot come back to life without medical intervention. However, to guarantee a death is irreversible, a period of time must elapse between cardiopulmonary failure and the declaration of death. The guarantee of irreversibility is based on very limited medical literature on autoresuscitation following cardiopulmonary arrest. The interval between cardiopulmonary failure (and therefore death) and the declaration of death is therefore essentially a measure of caution. In a context of organ donation, families and physicians agree in advance not to attempt to resuscitate after life-sustaining treatment has been terminated. This practice is particularly warranted when patients themselves have previously expressed the wish not to be resuscitated in such circumstances, for example, in a living will*. The Commission does not consider itself the appropriate authority to determine the most suitable time interval. However, it considers it important to make the following recommendation on the issue.

**Recommendation No. 5:**

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 pronunciation of death that would be scientifically and ethically acceptable and justified.

**Organ preservation methods: The risk of commodifying the human body**

During warm ischemia, organs deteriorate rapidly. To counteract this phenomenon, a solution can be injected in the arteries and abdomen to cool the organs and slow down the process. This is known as organ perfusion. It sometimes requires inserting cannulas in the femoral arteries*, which can be done before or after death. This is considered an invasive procedure and requires the donor’s or family’s free and informed consent.

To be viable for transplant, organs that have not been perfused must be removed very promptly after death. If the patient’s wishes regarding organ donation are unknown and the patient is unconscious, the medical team must seek the family’s consent before taking any action whatsoever in preparation for organ procurement. In some cases, it may be difficult to reach a member of the patient’s family before the patient dies, which results in a “loss” of transplantable organs.

For the family, perfusing organs for future harvesting can have positive and negative aspects. Firstly, perfusion gives the family time to say goodbye to a loved one and stay with the body longer, in the operating room. However, seeing a loved one connected to perfusion equipment can be overwhelming. But according to the healthcare workers consulted by the Commission, hospital staff are even more likely than families to be put off by antemortem cannula insertion.

In this regard, not all centers performing controlled CDC organ harvesting proceed in the same manner. While all agree on waiting for the family’s consent before cannulation and perfusion, some consider it better to insert cannula before death, while others proceed only after death. From an ethical standpoint, antemortem insertion facilitates organ retrieval, but is not a procedure performed in the best interests of the patient. Postmortem insertion may complicate organ retrieval, but respects the “do no harm” principle. **In the event that a CDC organ retrieval program is put into place, the Commission deems that the ethical and technical aspects of cannula insertion prior to death must be**
considered in much more detail in order to prevent any commodification of the human body and resolve the current lack of consensus on the matter.\textsuperscript{52}

\textbf{Using CDC donors in Canada: A practice not accepted by everybody}

In Canada, including Québec, patients who die from cardiac arrest are not considered potential organ donors. However, many countries have developed programs and protocols to govern organ retrieval from CDC donors and increase the number of transplant organs available. According to Knoll and Mahoney, the population supports the practice, as illustrates a recent study conducted in Southwestern Ontario in which the majority of respondents were in favor of organ retrieval from CDC donors.\textsuperscript{53} The authors report that a lack of awareness among healthcare professionals, a lack of resources in hospitals, and the fear of abuse are the main reasons organ retrieval from CDC donors is not practiced in Canada.

It is also important to note that the Canadian Critical Care Society (CCCS) has advocated a moratorium on CDC donation until public and professional consultations are held:

\begin{quote}
The CCCS calls for a moratorium on [CDC donation] protocols without prior national discussions among the population and representatives of professional groups, including physicians, nurses, main religious and cultural groups, and experts in health law, policy development, bioethics, and philosophy. The problems to be resolved include a) the impossibility of predicting the time of death, b) fears that cardiac death criteria do not meet the irreversibility criteria defined by law, and c) the emotional impact on the patient’s family in the operating room prior to death.\textsuperscript{54}
\end{quote}

The legitimacy of using cadaveric donors in cardiopulmonary arrest lies largely in whether it would significantly increase the organ pool. This issue goes hand in hand with determining whether organ procurement from cadaveric donors pronounced dead under brain death criteria (BDC) has achieved its full potential. On this issue, the report by Collège des médecins du Québec shows that in 2000, of the 348 potential donors identified, “268 cases of brain death (77\%) were diagnosed and recorded in the chart by at least one physician. In 230 of the cases (66\%), a request made to a family member appears in the file.”\textsuperscript{55} As such, much work remains to be done before it can be concluded that we have exploited the full potential of brain dead donors. Knoll and Mahoney believe that even if all BDC potential donors were identified, there would still be an organ shortage.\textsuperscript{56}

As for CDC, in 1999 two Alberta researchers published the results of a study conducted to determine the CDC potential for transplant kidneys.\textsuperscript{57} They reported that in 1995, 17 potential CDC donors were identified at their hospital, and concluded that a significant number of kidneys could have been retrieved. However, the impact of CDC donation can only be assessed if potential donors are recorded in hospital death records. After consulting members of the hospital community, the Commission believes it would be difficult to

\begin{footnotes}
\item[52] Institute of Medicine (2000), \textit{op. cit.}, pp. 50-52.
\item[56] G.A. Knoll and J.E. Mahoney, \textit{op. cit.}, p. 319.
\end{footnotes}
Position Statement of the Commission de l’éthique de la science et de la technologie

conduct such a study given the very circumstances surrounding the hospitalization of patients who may become potential CDC donors. In Spain in 2003, 46 of a total of 1,443 organ donors were CDC donors, providing organs for 87 transplantations.\(^{58}\)

The Commission noted a desire among those it met with for consultation of the population and healthcare workers. The Commission was particularly cautioned about the possible repercussions of proceeding without social acceptance for the practice—that the population would distrust organ donation and the popular belief would be reinforced that those who consent to organ donation do not receive all the treatment they need and are prematurely pronounced dead to access their organs. The population may also be suspicious of this intent to change the rules of the game, believing that harvesting as many organs as possible is the only motivation. That is why the Commission deems the population must be informed and consulted about the issue.

In addition, consultation with professionals in the hospital community remains an essential step in developing a CDC organ retrieval protocol. Hospital workers are the ones responsible for identifying potential donors, and their support is crucial to the success of such a protocol. However, some fear they could face criminal charges for CDC organ retrieval.\(^{59}\) Before they will follow the protocol, they must first be assured the practice is legal.

In February 2005, the Canadian Council for Donation and Transplantation (CCDT) will hold a conference in Vancouver on the subject of CDC, which is expected to advance discussions on the acceptability of the procedure. As such, the Commission makes the following recommendation.

**Recommendation No. 6:**

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

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\(^{58}\) Website of Organización Nacional de Trasplantes [http://www.msc.es/Diseno/informacionProfesional/profesional_trasplantes.htm]

\(^{59}\) These healthcare professionals are more specifically afraid of removing organs from patients who are not dead and facing homicide charges.
Chapter 3
Cadaveric donation consent models and raising the subject with families

Consent for organ donation is the essential prerequisite to harvesting organs from a deceased patient. Through consent, individuals are recognized for the autonomous people they are. However, this autonomy is not absolute. Other values and principles offset autonomy: beneficence, nonmaleficence, solidarity, and justice, to name just a few. There are two main consent models, each built on certain values: explicit consent (primarily personal autonomy) and presumed consent (primarily social solidarity). Several different scenarios are possible under these two models. Among them, the Commission chose to address mandated choice and setting up a registry. But whatever system is used, raising the issue with the family is a fundamental step in organ donation.

Consent models: Which model to choose?

Consent is of the utmost importance in the doctor-patient relationship, or, in research, in the researcher-subject relationship. It takes on a number of special qualities in organ donation, since the consent is not for medical treatment, much less for research. Individuals must give or withhold consent as provided for by law. In Québec, this means patients must provide written consent, or verbal consent before two witnesses. They can revoke this consent at any time in the same manner. When patients have not expressed their wishes, consent for organ donation is asked of the people who would have had the authority to consent to treatment, i.e., deceased patients’ families. Consent must be free and informed, as stressed in sources such as the Civil Code and Nouvelle encyclopédie de bioéthique. In addition, it must be “free of all outside influence, coercion, or manipulation of information.” The patient “must have understood the information provided by the physician,” and this information must be “as complete as possible and stated clearly and directly.” Lastly, “the consent must be given by a legally competent individual,” which excludes minors and incompetent adults.

The purpose of consent is to protect autonomy and the right to self-determination, integrity, and personal inviolability, as laid down by law and the Québec Charter of Human Rights and Freedoms. In addition, in article 17 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, the Council of Europe reasserts the importance of consent: “Organs or tissues shall not be removed from the body of a deceased person unless consent or authorization required by law has been obtained. The removal shall not be carried out if the person has objected to it.”

1. Civil Code of Québec, 1991, c. 64, art. 43.
2. Civil Code of Québec, 1991, c. 64, art. 10.
4. Ibid.
The American Society of Transplantation, in its *Statement on Ethics in Organ Transplantation*, very clearly states the underlying values of its positions on consent to organ donation:

Patients have a right to **autonomy**. The health care provider must respect an individual's personal, philosophical, and religious beliefs in making treatment decisions. The expressed wishes of competent, adult patients must be respected.

Similarly in the case of minors or incapacitated patients, the parents' or guardians' wishes must be respected. The **patient's well-being** is the goal.

The medical care of the donor is a crucial factor in transplant decisions. All decisions to donate must be made **freely** and without coercion or exploitation of any sort including financial or otherwise. Living donors, families and friends of living or cadaver donors should not profit financially nor should they be financially disadvantaged from donation.

To respect a **person's dignity** and **free choice**, donors must not be viewed primarily as a resource for transplants. A person should not be produced or created through sexual conjugation, cloning or any other means for the sole purpose of tissue or organ donation.  

That said, the Commission emphasizes that while consent must be free and informed, it may be either explicit or presumed.

**Explicit consent**

The explicit consent model is founded on two basic assumptions: to consent, individuals must clearly express their wish to donate their organs at death; to object, individuals are not required to take any particular action, other than possibly informing their loved ones of their objection.

In the past, Quebecers could consent to organ donation by signing the back of their driver's licenses. Led by Diane Hébert, the first Quebecer to receive a heart-lung transplant, the option became universal in 1987, along with the option of signing the health insurance cards held by all Quebecers. The two methods (driver’s licenses and health insurance cards) coexisted until 1992, when health insurance cards were made the only method because they were universal. Today, health card renewal mailings contain organ donation information sheets and consent stickers to place on the back of cards.

Legally, adults and minors aged 14 or over can consent to organ retrieval after death. Minors under the age of 14 can also consent with authorization from a parent or legal guardian. The *Civil Code* states that “these wishes are expressed verbally before two witnesses, or in writing, and may be revoked in the same manner,” and that “the expressed wishes must be followed, except for a compelling reason.” The concept of “compelling reason” is ambiguous and greatly complicates the interpretation of the law. According to a study commissioned by the organ and tissue donation committee at Centre hospitalier universitaire de Québec (CHUQ), 70% of physicians consider verbal or written consent by the donor’s family mandatory before beginning the organ or tissue donation process, even if the deceased has consented to organ donation. Hospital staff also raise the issue with families, including them in the potential donor’s medical evaluation process to avoid adding to their grief.

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7. *Civil Code of Quebec*, 1991, c. 64, art. 43.
8. *Ibid*.
The healthcare workers the Commission met with, including those responsible for approaching the family, generally confirmed that families who know the potential donor wished to donate rarely object to organ donation. In its statement on organ donation consent, the Danish Council of Ethics states the following:

The information received by the Danish Council of Ethics suggests that conflict between the deceased’s duly noted wish for donation and the next-of-kin’s rejection of that same wish arises in only very few cases. The problem is virtually academic, though this is not to say that the number of cases per se is decisive to the acceptability or not of disregarding the deceased’s consent.

However, it is essential for the debate on organ transplantation to make it clear that such clashes are confined to a very small number, so that in general the next-of-kin cannot be said to constitute a hindrance to organ donation when the deceased has given consent. Nor, then, is it possible to blame the unmet need for organs on any such conflict between the deceased and the next-of-kin.10

According to the Civil Code, “a part of the body of a deceased person may be removed in the absence of knowledge or presumed knowledge of the wishes of the deceased, with the consent of the person who could give consent to care or could have given it.”11 It goes on to say that “consent is not required where two physicians attest in writing to the impossibility of obtaining it in due time, the urgency of the operation and the serious hope of saving a human life or of improving its quality to an appreciable degree.”12 However, this provision of the law has never been invoked for organ retrieval. In general, the latest studies report that, regardless of whether the patient’s wishes are known, 50% to 70% of families give their consent.13

From an ethical standpoint, the explicit consent model promotes the personal autonomy of all individuals and the freedom to choose whether to donate their organs. It stresses the concept of donation “as a voluntary, personal gesture”14 that is authentic because the patient has personally made the decision to authorize organ retrieval at death. This model also emphasizes respect for integrity and inviolability, the right of control over one’s body, and the right to self-determination. It also offers the option of not making a decision on organ donation. Lastly, it upholds the voluntary nature of donation in all its generosity.

Presumed consent

The presumed consent model requires opting out of organ donation, instead of opting in. If an individual has not opted out, consent for organ donation is presumed and organ harvesting at death is authorized. There are two possible interpretations of presumed consent: strict (if the patient did not specifically object, organs can be harvested without the family’s consent) and conservative (if the patient did not specifically object, organs can...
be harvested only with the family’s consent). There are many ways of recording objections, but the most common is by setting up a registry and requiring people to have their names listed if they do not wish to donate.

The presumed consent model puts the emphasis on social solidarity, but strategic calculation can be the real reason for its adoption. In terms of social solidarity, Marie-Hélène Parizeau offers this explanation:

> The freedom of each individual to choose whether to be a potential donor conflicts with the social obligation to make one’s own organs available to others in the event of death. To some, social solidarity is a priority and obligation, just as everyone benefits from universal, free healthcare without regard to the volume of care received by any given individual.  

From social solidarity perspective, the community (its values, its interests) is at least as important as the individual. As such, social solidarity as a value should be given as much consideration as personal autonomy. Likewise, donation can also be considered a duty to share with the community. The authors of one position paper presented to the Commission stated that “if a person was aware of the right to refuse throughout his or her life but did not express a preference, assuming this person wished to donate organs recognizes the responsible individual’s commitment to solidarity and fulfillment of a moral obligation.”

From a strategic perspective, some countries are considering a presumed consent model primarily for utilitarian purposes. Under utilitarian ethics, a rule or action is morally right if it leads to the greatest happiness for the greatest number of people. Utilitarianism posits that the usefulness of a rule depends on the extent to which it achieves the value or goal. For example, if a rule like presumed consent tends to increase the number of organ donations, it should be considered morally right. However, it is no longer right if it has serious negative consequences that outweigh its benefits.

Experts are divided as to the impact presumed consent has on the organ pool. While some point out that the number of donors has increased in countries that have adopted presumed consent, others suggest the increase is due to the higher number of organ transplant centers or awareness campaigns aimed at the population and healthcare professionals.

In a survey conducted by the United Network for Organ Sharing (UNOS) in the U.S., more than half of physicians reported being opposed to presumed consent. The main reason cited was that donors should have a choice. In theory, presumed consent does not preclude the freedom to choose. However, those who are not sufficiently informed of the possibility of refusing no longer have a choice—consent is presumed. This survey shows

15. Ibid.
that the concept of presumed consent is not fully understood. If presumed consent were to be adopted without an education campaign, there would therefore be a risk that healthcare workers and the population would oppose the model and ultimately show less sympathy for organ donation.\textsuperscript{20}

However, in a recent survey conducted for the Commission, 55\% of respondents were very much or somewhat in favor of presumed consent.\textsuperscript{21}

**Mandated choice and the setting up of a registry**

Among the scenarios that could be integrated into the consent models described above are the introduction of a mandated choice system or a donor or consent registry. The Commission chose to explore these two scenarios due to their growing support abroad as potential strategies to alleviate the organ shortage.

**Mandated choice** is a mechanism by which all those deemed able to consent would be required to declare their wishes about organ donation. They would, however, be permitted to change their minds. In some cases, their choice could be binding, and the family would not have the right to reverse a potential donor’s decision.

In Canada and Western society as a whole, the vast majority of the population seems to be in favor of organ donation. However, while people agree in theory, this does not mean they always give consent.\textsuperscript{22} If mandated choice is backed by a registry to compile the data, it could be very flexible. Donors’ specific wishes could be recorded, such as which organs or tissues they would be willing to donate or even whether they prefer to leave the decision to a family member. This type of strategy could, however, be considered intrusive, in that there would be no right to indecision, unless a choice like “undecided” were included in the options.

Lastly, some studies seem to show that the greatest obstacle to organ donation, in the absence of donors’ clearly expressed wishes, is family refusal.\textsuperscript{23} If everyone were to clearly state their wishes, the number of donations should, in all likelihood, rise. But with mandated choice, people answer when they are in good health, but perhaps not ready to consider their future death and the possibility of organ donation.\textsuperscript{24} It therefore entails risks. For example, it could lead to high refusal rates, to the chagrin of organ donation advocates. A case in point is Texas, where 80\% of those required to complete organ donor cards\textsuperscript{25} elected to refuse consent. Moreover, the organ donation and transplantation professionals consulted by the Commission indicated that the mandatory aspect of the approach could be decried, despite the fact that 67\% of respondents to the survey conducted for the Commission were somewhat or very much in favor of mandated choice.\textsuperscript{26}


\textsuperscript{21. See Appendix 1 for a summary of the results of the Commission’s mini-survey.}

\textsuperscript{22. According to a survey conducted in March 2004 by Léger Marketing, 73\% of Quebecers would agree to donate their organs, but nearly half had not yet taken the steps required to express this preference.}


\textsuperscript{26. See appendix 1 for a summary of the results of the Commission’s mini-survey.}
Setting up a **donor or consent registry** consists of compiling in a single database the names of those who have consented to donate their organs at death.

Recently, Chambre des notaires du Québec decided to create an organ donation consent registry for Québec. The project instigators present it in the following terms:

Given that the organ shortage is an insurmountable obstacle to providing lifesaving treatment for patients awaiting an organ, and given the desire of all medical professionals to improve the lives of potential organ recipients, Chambre des notaires wishes to propose the creation of an organ donation consent registry that both protects the confidentiality of the information compiled and oversees its collection, use, disclosure, and consultation.

There are considerable advantages to a consent registry. According to Dr. Gordon Crelinsten, chair of the Canadian Medical Association Ethics Committee, “One of the merits of such a registry is that it can increase the supply of organs while safeguarding the value of personal choice and free giving.” This is also the opinion of the American Medical Association’s Council on Ethical and Judicial Affairs. As for the Commission, it deems that a registry of this nature may reassure patients they will receive the best possible care until the very end. As mentioned above, hospital staff indicated that some people fear not receiving the care they need if they have already consented to organ donation. The registry would reassure them by keeping their consent confidential. To do so, the system would have to be structured such that physicians would have access to it only after death is declared.

On the other hand, a registry also raises problems regarding factors such as management cost, accessibility, irreversibility, and updating. Experience in Belgium and France has shown, for example, that the cost of creating and managing this type of registry can be prohibitive. An update mechanism would also have to be put in place for people who change their minds. In North America today, Ontario, British Columbia, Nova Scotia, and a number of U.S. states have voluntary donor registries in place, allowing people to express and register their wishes on a noncompulsory basis. In a report published in February 2002, the U.S. Department of Health and Human Services concluded that organ donor registries are very useful, but only slightly increase the number of organ donations. Lastly, even with a registry in place, people would still have to notify their family members, since healthcare workers will in all likelihood continue to request the family’s consent before proceeding.

### Maintaining the actual formula

Experience in other countries tends to show that presumed consent has no tangible impact on the number of organ donors. And even if the model were instituted in Québec, we would still continue to seek family consent, which is a firmly rooted practice in hospitals out of respect for families and their needs. Families are also in the best position to know their loved ones’ last wishes and whether they may have recently changed their minds. A government-imposed mandated choice system or donor or consent registry offers very few advantages.

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benefits compared to the risks and drawbacks. **In the Commission’s opinion, the explicit consent model currently in place has proven effective and continues to reflect the fundamental values of Québec society.**

**Raising the subject with families: Ensuring respect, autonomy, and trust**

A family’s response to the request for a loved one’s organs largely depends on the way healthcare workers approach the family, and their ability to create a climate of trust. In this respect, an article recently published in the journal *Perspective Infirmière* listed a set of rules to follow when approaching the family (see inset).

**How to approach the family**

- Meet with families in a private, comfortable place.
- Give them clear, precise information on the prognosis and diagnosis of brain death, avoiding the terms “serious,” “severe,” and “critical.”
- Answer their questions in simple terms, and repeat if necessary.
- Before offering families the option of donating organs, give them time to take in the loss of a loved one, and never pressure families to consent.
- Address the issue of organ donation with empathy and compassion, allowing families to articulate and express their emotions.
- Be sensitive to their grief, offer them pastoral care, and give them literature on bereavement and community resources.
- Listen to their needs and respect their emotions, beliefs, sensitivity, and fears.
- Explain the benefits of transplantation, the comfort they can gain from organ donation, [and that] the body can still be viewed before the funeral.
- Assure them their choice will be respected and they will be supported regardless of their decision.

But whatever the rules, they serve no purpose if families are not approached. The study by Collège des médecins du Québec on potential donors in 2000 revealed that “only 76% of families received a request for organ donation when brain death was diagnosed.”

According to a study commissioned by the organ and tissue donation committee at Centre hospitalier universitaire de Québec (CHUQ), “nearly 8 out of 10 physicians consider it quite arduous to approach donors’ families.” In fact, many healthcare workers are uncomfortable, since most are not trained on approaching the family in such situations. In this regard, the Council of Europe recommends the following:

> People should be encouraged to speak about organ donation and transplantation and to communicate their wishes to their relatives. As a donor’s wishes will not always be known, staff in a position to make requests for agreement to organ donation to relatives should be properly trained for the purpose. If such requests are well handled the rate of donation refusals can be reduced.

35. Council of Europe, Meeting the organ shortage: current status and strategies for improvement of organ donation, [online], 1999. [http://www.social.coe.int/fr/qdevie/publi/greffe.htm]
Here at home, Canada’s National Coordinating Committee for Organ and Tissue Donation and Transplantation considers it the responsibility of “health regions” and “hospitals,” among others, to “provide the resources for bereavement support personnel to be part of the critical care team,” and to “provide private areas for families to congregate and grieve and participate in religious rituals as approved by hospital/regional authorities.”

In terms of approaching the family, the Commission embraces three closely related fundamental values—respect, autonomy, and trust. All those taking part in raising the issue of organ donation with families must demonstrate these values.

An approach based on respect

In the consultations held by the Commission, it was clear that respect must be a guiding value whenever a family is approached about organ donation. According to the Council of Europe—

The approach to the relatives of a potential donor is another of the key steps in the transplant process and one of the most sensitive given that it necessarily coincides with the distress and trauma surrounding any death, particularly if that death is sudden or unexpected as is so often the case when the patient is young.

It is important to remember the family is first and foremost the family of a patient who is about to die or has just died, not that of an organ donor. The family is in the earliest stage of grieving, with everything that implies. In Québec, more and more is being done to provide family support during this emotionally difficult time, but a lack of resources in the field limits the quality of this support. The Commission considers it important that those who approach the family about organ donation remain neutral and do not present consent as the expected decision or refusal as a disappointing one.

While organ donation can facilitate the grieving process when properly presented, it can also disastrously interfere. A recent study conducted in the Netherlands concluded that family dissatisfaction with the way they were approached by healthcare workers was associated with depressive symptoms. That is why resource nurses in Québec hospitals support families regardless of their decision on organ donation. They are rarely the ones to approach families about organ donation. This shows that the family approach involves not only organ donation, but also support and respect for bereaved families. Resource nurses are also responsible for raising awareness among other hospital staff that may approach the family to both announce death and ask about organ donation. Lastly, it is important to add that respect is crucial despite the fact that time is of the essence in organ retrieval.

An approach based on autonomy

In approaching families, a certain emphasis must be placed on explaining things. Families find themselves in a hospital setting that is governed by its own standards and, over the years, has developed its own specific vocabulary, practices, and protocols. Hospital staff

36. National Coordinating Committee for Organ and Tissue Donation and Transplantation, A Coordinated and Comprehensive Donation and Transplantation Strategy for Canada, report presented to the Federal/Provincial/Territorial Advisory Committee on Health Services, Canada, November 30, 1999. Note that this committee was not permanent and was dissolved after presenting its report.


must help them understand the dynamics of this setting, without imposing their own points of view.

The primary purpose of informing families must be to respect their needs, including their need to understand their loved one’s condition, the causes, the chances of survival, and the options available. This discussion is also an opportunity to give families the autonomy they need to make informed decisions about organ donation. In this regard, the lack of information was identified in the Commission’s consultation as a factor associated with the refusal of organ donation.

In addition to information concerning the patient in question, various concepts must also be explained, such as that of brain death. In 1998, researchers found that combining three elements in the request process could significantly increase family consent rates, namely ensuring the family understands and accepts the concept of “brain death” before organ donation is discussed, involving a coordinator in the request process, and approaching the family in a quiet, private place. According to a U.S. study, brain death was explained to virtually all (96%) families of potential donors, but only 28.3% of families were able to give an accurate and full definition. The study also revealed that families who had accepted the diagnosis of brain death were more inclined to consent to organ donation than those of patients who were not pronounced dead until treatment to artificially maintain heart and lung functions was terminated and their hearts stopped beating.

Families seem to want more information on the organ donation and transplantation process to help them make informed decisions. It is also important to give certain information to families who are undecided or have refused donation. For example, some families may change their minds when they learn there is no additional cost and the body can still be viewed. In fact, these are two oft-cited reasons in surveys for refusing organ donation. From an ethical standpoint, families must be able to make informed decisions, whether for or against donation. Providing families with all the information they need to make informed decisions both allows and encourages them to act autonomously.

The question of timing in the request process was another concern raised by healthcare professionals and researchers. UK Transplant, the body responsible for coordinating donation and transplantation in Great Britain, advocates raising the subject with families as soon as they understand death is imminent. Yet researchers Niles and Mattice found no significant difference in family reactions based on whether the request was made before or after death was announced. The researchers added, however, that when families were notified of death and asked for consent at the same time, the consent rate dropped from 69% to 37%.

In Québec, some centers prefer to explain the diagnosis to the family as soon as the patient shows signs of impending neurological death. This approach is based on clinical experience that appears to show a higher consent rate when families are asked about organ donation in advance, when the atmosphere is usually more conducive.

42. UK Transplant, *United Kingdom Hospital Policy for Organ and Tissue Donation*, Bristol, April 2003, p. 4.
44. Notably at Hôpital de l’Enfant-Jésus de Québec, a center serving all of Eastern Québec for donor referral.
An approach based on trust

Respect for donor families and their autonomy is the basis for developing a trusting relationship with representatives of the organ donation coordinating agency and healthcare workers. The professionals in question reported to the Commission that the more time they spent with families, the higher the consent rate.

To strengthen the sense of trust, donor families must also be assured follow-up. In Québec, three or four weeks after families consent to donation, they are contacted by Québec-Transplant. Organization representatives then answer their questions and inform them of the recipients’ health. Recipients who wish to thank the families of cadaveric donors can do so in an anonymous letter forwarded through Québec-Transplant. At the round table organized by the Commission on consent and approaching the family, attendees explained that many families welcomed these words of thanks and found they helped with the grieving process.

A commendable Québec initiative: Resource nurses

In Québec, in the wake of the 1997 proposal by the Committee on Organ and Tissue Donation and Transplants, Québec-Transplant set up a pilot project providing hospitals with resource nurses to support families, help identify potential donors, and inform healthcare teams of the possibility of donation and the steps to take if consent is obtained. In its 2001-2002 annual report, Québec-Transplant described resource nurses as follows:

Their role is to coordinate all activities surrounding organ and tissue donation at the hospital. Their involvement with the parties concerned at all stages of organ donation, from identifying the potential donor to transfer and organ retrieval, facilitates the organ and tissue donation process. Their primary role, after identification, is to approach and support the family throughout the process and provide follow-up care.

In January 2002, the first ten resource nurses trained by Québec-Transplant went to work in seven hospitals. In fall of the same year, another seven hospitals received resource nurses, bringing the total to fourteen. By March 2003, there were twenty-three resource nurses working in twenty hospitals.

The Commission gathered comments from hospital staff at a round table on consent and approaching the family in spring 2004. Staff had noticed that since the resource nurse program had been put in place, not only had consent rates increased, but families were also more satisfied with the support they received. These observations bear out the results reported by Québec-Transplant:

Organ donation and transplantation resource nurses, who were fully in place by the end of the last fiscal year, clearly contributed to the rise in our coordination activities during the year. […]

Their skill in approaching the family and providing support contributed to the increase in family consent for organ donation following a brain death. The consent rate as a percentage of referrals climbed from 77% at the end of 2002-2003 to 83.4% at the end of the current fiscal year. One hundred and thirty-five of 153 actual donors were referred by these hospitals.

45. Committee on Organ and Tissue Donations and Transplants, *Organ and Tissue Donations and Transplants in Québec*, July 1997, p. 27.
Chapter 4
Organ distribution: The challenge of distributing a rare resource

Transplant candidate selection and organ distribution are two processes that pave the way to an operation for patients whose quality of life, and in some cases, survival, hinges on a transplant. If there were sufficient numbers of organs available to meet demand, the transplant candidate selection and organ distribution processes would likely not be giving rise to such agonizing choices. However, given the current organ shortage, these two processes have raised a number of ethical dilemmas focusing on the key values of fairness, effectiveness, and safety. The interrelationship between these values is complex, which makes it considerably more difficult to address them simultaneously, and poses major ethical challenges.

Selecting transplant candidates: toward clearer criteria

It is important to begin by making the distinction between the transplant candidate selection and the organ distribution processes. Candidate selection is the process by which, following a specialist’s diagnosis, a patient’s name may be added to the official Québec-Transplant waiting list, which is used for organ assignment purposes. This is the first step in obtaining an organ, although physicians can make no guarantees as to the likelihood of receiving an organ. Depending on the required organ and the degree of urgency for the patient in question, the waiting period before the desired organ is offered can range from a few days to several months.1

The healthcare practitioners charged with assessing candidates examine two types of factors—medical and psychosocial.

It should be noted that medical factors vary depending on the required organ. Generally speaking, the medical factors that carry the most weight in the decision whether to add a candidate’s name to the waiting list include positive HIV serology, presence of cancer, a multisystem illness, positive hepatitis serology, the degree of clinical incapacity, and general health.2 In recent years, there has been a decrease in the number of exclusion criteria and in the contraindications applicable to patients wishing to be added to the waiting list.

The determining psychosocial factors include candidate motivation, understanding of transplant risks and benefits, presence of a support network, and, most importantly, a willingness to take anti-rejection drugs. That being said, certain psychosocial factors can, like medical criteria, constitute exclusion criteria. These can include a candidate’s refusal, excessive use of drugs—including alcohol and medication—and lack of compliance with doctor’s orders. These last two factors provide some idea of the overlapping of medical and psychosocial criteria. In fact, certain factors considered psychosocial can have an impact in medical terms and therefore become medical factors themselves. For example, while alcohol abuse is considered a psychosocial factor, from a strictly medical standpoint it reduces the chances of success of a transplant.

1. See Table IV in Appendix 2 for average waiting periods.
Medical factors, regardless of the type of organ transplant, generally appear to carry more weight in the selection of patients to the waiting list. Moreover, the impact of other factors tends to depend on whether or not they have an incidence on the patient’s state of health. In short, healthcare workers who are involved in selecting transplant candidates base their decisions on the chances of the transplant succeeding rather than on moral judgments, for example. Certain factors are considered to have little or no bearing. These include social status, economic status, place of residence, and interest in taking part in research studies. However, the Commission wishes to stress that it gathered testimonials that revealed that support from the patient’s loved ones is an important factor in determining which patients are added to the waiting list. The Commission has made the following recommendation with regard to selection criteria for transplant candidates.

**Recommendation No. 7:**
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

The Commission has observed that, depending on the type of organ in question, the importance of psychosocial factors varies considerably. For heart, lung, liver, and pancreatic transplants, psychosocial factors play a much more central role, since a transplant is the only solution to extending the life of these patients to any significant degree. The deciding factor in these types of transplants generally hinges on the effectiveness of the transplant. In the case of kidney transplants, patients awaiting organs can benefit from hemodialysis treatments for a certain time. As a result, healthcare workers involved in kidney transplants generally adopt a position of “fairness and equality, which translates into a commitment to providing a chance to the greatest number of candidates possible.”

These two philosophies represent the prevailing trends in the selection of transplant candidates. The first consists of screening candidates more closely to ensure that those who are named to the waiting list have the greatest chance of a successful transplant. The second aims to give the maximum number of patients a chance at receiving an organ. While the first philosophy focuses on effectiveness, the second strives for fairness above all.

There is thus a certain discord between the two schools of thought that can be summarized as follows:

On one hand, given the shortage of available organs versus demand, and with a view to handling requests fairly and providing all patients with an equal chance at obtaining the required organ, a certain concern for justice underlies the various selection stages. On the other hand, the shortage of organs together with the need to control healthcare costs has led to an increasing focus on the effectiveness of transplants, both in terms of the individual patient and the health system in general.

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Each center (and transplant team) has its own transplant candidate selection policies and adopts the philosophy it deems the most suitable. Yet differences are minimal, and each transplant team or center’s philosophy is in keeping with the latest scientific and technological developments. However, it must be noted that there is a slight disparity across Canada in the way transplant candidates are assessed, even for the same types of transplant. In a report released in February 2000, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) made the following observation:

The survey results demonstrate that heart, cadaveric kidney, and liver centers in Canada generally practice similar methods of listing patients awaiting transplantation. However, the degree of importance given to certain patient criteria varies, both within a particular organ group and between organ types. Differences between centers within a solid organ type were observed in the priority given to such criteria as recipient age (kidney), employment status (heart), recipient nationality, and mental competence (liver). The degree of importance given to factors such as tobacco use, and the requirement for established programs for social and community support, vary among the solid organ types.6

Transplant selection criteria policies have never been standardized in Quebec or elsewhere in Canada, except for kidney transplants, for which nationwide eligibility criteria have been established.7 The goal of this ambitious (some would say, idealistic) standardization project is to ensure a fairer transplant candidate assessment system, particularly in terms of psychosocial criteria. Without a standardized system in place, there is a risk that centers intent on presenting an impressive statistical record would accept only those candidates with a high probability of a successful transplant, while other centers committed to offering all candidates a fair chance would accept candidates with a higher risk of transplant failure. This concern is the focus of a recommendation by CCOHTA:

[...] it would be of benefit to standardize organ-specific criteria at the national level for patients waiting for heart, cadaveric kidney, and liver transplantation to ensure equitable access to this public resource in Canada. This is of paramount importance given that there are ethical and social implications associated with the factors under consideration. Criteria for patient listing have implications for human rights and access to health care, informed consent, and the role of control and responsibility for illness.8

It is important to recall that physicians are required to be as objective as possible in making decisions with regard to their patients and that they must be encouraged to remain so when it comes to transplants. However, in the event patients question their physician’s objectivity, the Code of Ethics of Physicians stipulates that “A physician must acknowledge the patient’s right to consult a colleague, another professional or any other competent person. He must not, by any means, interfere with the patient’s freedom of choice.”9 Therefore, physicians who refuse to put their patients on the waiting list due to shortage of equipment or expertise or psychosocial criteria must offer them the option of seeking out a second medical opinion in another hospital.

On the whole, the Commission believes that transplant candidate selection criteria should not be standardized, although standardization of certain criteria could be an attractive compromise. Standardizing the criteria could take away the flexibility transplant centers and teams require to adapt to specific local circumstances. However, standardization initiatives would help reduce the risk of discrimination against patients.

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Organ distribution: distributing a rare resource

Distributing a rare resource like vital organs is no easy task. The process must comply with well-established procedures and is subject to constraints such as the length of time an organ can remain outside of the human body. In the following pages, the Commission explains the organ distribution process, including the criteria used to determine how organs are distributed, as well as issues of transplant safety.

The organ distribution process

In Canada, management of the organ distribution process is a provincial responsibility, except for emergency heart and liver transplant cases. The federal government, through its Standing Committee on Health, has examined the possibility of creating a Canadian transplant network with a nationwide waiting list. However, this project has its limits, namely the maximum time an organ can remain outside the body before losing its transplant viability. Table 4 gives an approximation of the average acceptable cold ischemic* times.

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Average acceptable cold ischemic* time per organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organ</td>
<td>Maximum ischemic time</td>
</tr>
<tr>
<td>Kidney</td>
<td>18 hours</td>
</tr>
<tr>
<td>Liver</td>
<td>8 hours</td>
</tr>
<tr>
<td>Pancreas</td>
<td>8 hours</td>
</tr>
<tr>
<td>Lungs</td>
<td>4.5 hours</td>
</tr>
<tr>
<td>Heart</td>
<td>4 hours</td>
</tr>
<tr>
<td>Heart-Lungs</td>
<td>2 hours</td>
</tr>
</tbody>
</table>

In Québec, Québec-Transplant and transplant centers and teams share responsibility for distributing organs and keeping the waiting list up-to-date. The order in which recipients appear on the list is determined based on the transplant organs available and organ distribution criteria. The distribution criteria are readily available to the public, notably via Québec-Transplant’s website. For obvious reasons of privacy protection and confidentiality of medical records, which take precedence over transparency, the names of people on transplant waiting lists are not made available to the public. The matter of transparency is addressed otherwise. Establishing rules that apply across the board and that are made clear to all involved can go a long way to making the organ distribution process more transparent. When Québec-Transplant is notified that an organ is available, it contacts the transplant centers to offer it to them.

10. See heart and liver distribution criteria below.
Organ distribution criteria\textsuperscript{14}

As mentioned above, organs are distributed differently depending on the organ harvested. These differences can be 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 outlines hereafter the distribution criteria for each organ along with comments regarding ethical issues, where applicable.

Heart

The distribution of hearts is based on the clinical status of patients awaiting a transplant. Clinical status is divided into categories into which waiting patients fall depending on their state of health (see inset)

<table>
<thead>
<tr>
<th>Clinical status used to determine heart distribution (in order of priority)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Status 4</strong></td>
</tr>
<tr>
<td>Patients under mechanical support: mechanical heart, ventricular assistance, intra-aortic balloon, or respirator, and patients in an intensive care unit.</td>
</tr>
<tr>
<td><strong>Status 3b</strong></td>
</tr>
<tr>
<td>Patients hospitalized in an intensive care unit (or equivalent) under continuous inotrope infusion or vasopressors. This category also includes patients with ventricular assistance devices hospitalized in intensive care units.</td>
</tr>
<tr>
<td><strong>Status 3a</strong></td>
</tr>
<tr>
<td>Patients with ventricular assistance devices or who are receiving intermittent inotrope infusions. Patients may be at home or hospitalized outside an intensive care unit (or equivalent).</td>
</tr>
<tr>
<td><strong>Status 2</strong></td>
</tr>
<tr>
<td>Patients hospitalized outside an intensive care unit (or equivalent)</td>
</tr>
<tr>
<td><strong>Status 1</strong></td>
</tr>
<tr>
<td>Patients at home</td>
</tr>
<tr>
<td><strong>Status 0</strong></td>
</tr>
<tr>
<td>Patients temporarily removed from the list Quebec-Transplant must be notified of reason for removal.</td>
</tr>
<tr>
<td><strong>Status X</strong></td>
</tr>
<tr>
<td>Patients permanently removed from the list Quebec-Transplant must be notified of reason for removal.</td>
</tr>
</tbody>
</table>

\textsuperscript{14} Criteria in effect on August 1, 2004, but currently under revision.

\textsuperscript{15} QUÉBEC-TRANSPLANT, PRO-C-101 Heart Attribution.
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According to Québec-Transplant, when a heart becomes available for transplant, “Priority is given to ABO compatible recipients on the waiting list according to their clinical status, from most to least urgent (status 4 to 1).”\(^\text{16}\) In addition, “For patients of equal status, waiting time will determine the order of priority.”\(^\text{17}\) This means that heart recipients whose blood is compatible with the donor are first in line, followed by patients with the following clinical status (in order)\(^\text{18}\):

1. Status 4 (in Québec)
2. Eisenmenger Syndrome* (in Québec)
3. Status 3b (in Québec)
4. Status 3a (in Québec)
5. Status 4 (outside Québec)
6. Status 2 (in Québec)
7. Status 1 (in Québec)

If no recipient is found for the heart in Québec, it is offered to the nationwide waiting list in order of priority.

Given the urgency with which they require a heart, Status 4 patients are in a category apart. A Canadian list of Status 4 patients awaiting heart transplants has been drawn up. It is therefore possible for a heart to be attributed to a Status 4 patient outside the province, but “only if there are no Status 3 (b and a) or 4 recipients in Québec at the time of attribution.”\(^\text{19}\) At this stage, if there are no compatible recipients on the Canada-wide list, Québec-Transplant will make the heart available to Status 2 and 1 patients on the provincial list before offering them again to the national list. If two or more recipients have equal clinical status, the organ will be attributed to the recipient who has been on the waiting list the longest.

With regard to urgent status recipients on the provincial list (Status 4, 3b, or 3a), compatibility is the only attribution criteria. Québec-Transplant notes that “if there are no urgent status Group “O” heart recipients on the list, Group “O” hearts will be offered first to Group ‘O’ recipients.”\(^\text{20}\) Hearts offered through programs outside Québec to one or more patients in Québec will be attributed in accordance with Québec-Transplant’s protocol.

When it comes to organ distribution, exclusion criteria must also be taken into consideration:\(^\text{21}\):

- Incompatible body measurements
- Age of the donor as per the transplant team’s judgment
- Cardiac function and angiogram as per the transplant team’s judgment
- Positive crossmatch to the recipients for whom the result of the test is a prerequisite for the transplant
- Maximum cold ischemia/maximum distance as per the transplant team’s judgment
- Other points noted at the time of listing

\(^\text{16. Ibid.}\)
\(^\text{17. Ibid.}\)
\(^\text{18. Ibid.}\)
\(^\text{19. Ibid.}\)
\(^\text{20. Ibid.}\)
\(^\text{21. Ibid.}\)
If a crossmatch* is not available before the transplant (delay for laboratory results or organs coming from outside Québec), the decision to proceed is up to the transplant surgeon.

**Liver**

Like hearts, livers are attributed according to the clinical status of patients awaiting transplantation (see inset).

### Clinical status used to determine liver distribution (in order of priority)

#### Status 4F
Hospitalized recipients in the intensive care unit, intubated, with a diagnosis of fulminant hepatitis or retransplantation (including the diagnosis of primary non-function) and for whom death is considered imminent without a liver transplantation

#### Status 4
Hospitalized recipients in the intensive care unit, intubated, with a diagnosis of a severe liver disease excluding fulminant hepatitis and for whom death is considered imminent without a liver transplantation

#### Status 3F
Hospitalized recipients in the intensive care unit with a diagnosis of fulminant hepatitis and without any mechanical support. Recipients must meet the King’s College criteria and be considered at a high risk of mortality without a liver transplantation

#### Status 3
Hospitalized recipients in the intensive care unit with a diagnosis of acute liver disease, without mechanical support and fulfilling one or more of the following criteria:
- Serum creatinine level > 200umol/L and/or over 50 umol/day (adult)
- Serum creatinine level more than double the normal for the age of the recipient (pediatric)
- Grade III or IV encephalopathy
- Upper GI bleeding difficult to control

#### Status 2
Hospitalized recipients with stable clinical status or awaiting a liver/bowel transplantation

#### Status 1
Recipient at home

#### Status 0
Recipient temporarily withdrawn from the list. Patient must be reevaluated at least once a month. Québec-Transplant must be notified of the reason for withdrawal:
- Improved health
- Patient too sick or infection
- Patient refuses transplantation
Once a liver becomes available for transplant, “priority is always given to the recipient with the most urgent status.” Certain Canadian organ exchange agreements must be complied with for Status 4F, 4, and 3F patients. Québec-Transplant defines liver attribution priority as follows:

**First priority:**
Priority is accorded to Status 4F recipients on the national list before Status 4 or lower recipients on the Québec list. However, Status 4F recipients on the Québec list have priority over Status 4F recipients on the Canadian list. Waiting time of urgent status recipients is taken into consideration for recipients from other regions of Canada only.

**Second priority:**
Priority is accorded to Status 4 recipients on the national list before Status 3F or lower recipients on the Québec list. However, Status 4 recipients on the Québec list have priority over Status 4 recipients on the Canadian list.

**Third priority:**
Priority is accorded to Status 3F recipients on the national list before Status 3 or lower recipients on the Québec list. The Canadian program physician involved in the case must contact the Québec physician with priority at the time of attribution.

It is up to the physicians involved to decide whether the liver will go to the urgent status recipient and if a reciprocity mechanism will be put in place in the event the liver cannot be transplanted in the urgent status recipient, for whatever reason. However, Status 4F, 4, and 3F recipients in Québec have priority over Status 3F recipients in the rest of Canada.

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22. QUÉBEC-TRANSPLANT, PRO-C-105 Liver Attribution.
23. Ibid.
24. As with hearts, livers received from outside Québec will be attributed in accordance with the established protocol and in order of priority.
25. QUÉBEC-TRANSPLANT, PRO-C-105 Liver Attribution.
With regard to blood group compatibility, Québec-Transplant notes the following:

For urgent status (3F, 4, and 4F) patients, organs are attributed without regard for blood group. For Status 3 or lower patients, priority is given to recipients whose blood group is compatible with the donor’s. For a Group O donor, priority will go to a Group O recipient, unless there is a Status 3 or higher recipient on the waiting list. However, for pediatric recipients, all the blood group compatible livers must be offered according to the patients’ order on the waiting list. The liver of a Group O donor will be offered to Group A, B, and AB recipients only after it has been turned down by all Group O and pediatric recipients (a Quebec requirement).26

For recipients with liver neoplasia* and/or tyrosinemia*, organs are attributed according to their exception status. For instance, patients with liver neoplasia (with the exception of bile duct neoplasia) are listed according to their clinical status and are given priority only over other Status 1 recipients. Recipients suffering from tyrosinemia with nodules are listed at least as Status 2 and have priority over all other recipients with the same status. Special status is also accorded to pediatric patients. “Recipients aged 0 to 12 years at the time of listing have their status increased by one level.”27 A desire for fairness is therefore reflected in these measures and can affect the clinical status of certain patients.

The donor’s weight and height must be compatible with the weight and height of the recipient. Specific criteria may be required, in particular for children, even if the pediatric transplantation team decides to use a reduced liver.

On the matter of crossmatching, “it is up to each transplantation team to decide whether a donor/recipient crossmatch is required.”28

**Lungs**

The attribution criteria for lungs are somewhat different from those for hearts and livers, for which clinical status plays a determining role. For lungs, “clinical status of the recipients on the provincial waiting list is used for reference purposes only, not to determine attribution. The exception to this rule is when an organ comes from outside Quebec, in which case this classification is always used.”29 (see inset)

**Clinical status used to determine lung distribution (in order of priority)**

<table>
<thead>
<tr>
<th>Status 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstable, rapidly deteriorating recipients:</td>
</tr>
<tr>
<td>– Hospitalized for rapid deterioration of their clinical status</td>
</tr>
<tr>
<td>– Not hospitalized but receiving at least 4 liters of O2/minute</td>
</tr>
<tr>
<td>– Not hospitalized but under ventilatory support</td>
</tr>
<tr>
<td>– Not hospitalized but under IV pulmonary vasodilators at an increasing rate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Status 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable recipients who do not correspond to any of the criteria mentioned above (Status 2)</td>
</tr>
</tbody>
</table>

Québec-Transplant30

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26. Ibid.
27. Ibid.
28. Ibid.
29. QUÉBEC-TRANSPLANT, PRO-C-103 Lung Attribution.
30. Ibid.
The main lung attribution criterion is to give priority “to identical ABO recipients on the waiting list in order of the date and time of listing, from the earliest to the most recent.” Lungs will be offered outside Quebec only if there are no compatible recipients on the provincial waiting list. Lungs offered through programs outside Quebec for one or more patients in Quebec will be attributed as per the Quebec-Transplant protocol, taking into account the classification of clinical status in effect across Canada (Status 1 and 2).

Certain exclusion criteria apply to lung attribution:

- Incompatible body measurements
- Age of the donor as per the judgment of the transplantation team
- Pulmonary function and x-rays as per the judgment of the transplantation team
- Positive crossmatch (50% or more) for recipients with a PRA >20%, as per the judgment of the transplantation team
- Maximum cold ischemia/maximum distance as per the judgment of the transplantation team
- Other factors noted at the time of listing

Kidneys

Compatibility plays a central role in kidney attribution. ABO blood compatibility, for instance, is required to ensure the success of the transplant. Kidneys are attributed to ABO compatible recipients with a negative crossmatch as determined by one of the laboratories associated with Quebec-Transplant.

However, “Absolute priority is given to ABO-compatible recipients who have been deemed medical emergency cases according to the policy Listing of a recipient on the kidney emergency list.” This also applies to patients awaiting two organs other than a kidney/pancreas combination.

Kidney recipients must not only be ABO compatible, there must also be absolutely no HLA incompatibility:

Priority is given to ABO-compatible recipients with no incompatibility with the donor’s HLA/ A, B or DR loci. Subsequent priority is given to recipients with the lowest HLA B and DR antigen incompatibility with the donor. Recipients are ranked according to the score they obtain, in descending order, as shown below [Table 5]:

<table>
<thead>
<tr>
<th>Degree of incompatibility</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HLA-B</td>
</tr>
<tr>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 5

Score based on HLA incompatibility

31. Ibid.
32. Ibid.
33. Ibid.
34. QUÉBEC-TRANSPLANT, PRO-C-104 Kidney and Kidney/Pancreas Attribution.
35. Ibid.
36. Ibid.
Unless there is a recipient with no incompatibility, kidneys will be attributed as follows:

- Group “O” kidneys are attributed to Group “O” and “B” recipients
- Group “A” kidneys are attributed to Group “A” and “AB” recipients
- Group “B” kidneys are attributed to Group “B” and “AB” recipients
- Group “AB” kidneys are attributed to Group “AB” recipients

For the same score, kidney/pancreas patients have priority over patients awaiting a kidney only. Where a number of patients awaiting a kidney only have the same score, the organs will be attributed as follows:

1. Priority is given to children aged 15 or under
2. Priority is given to recipients who have, or have had in the past, 50% or more circulating antibodies
3. When a number of patients have the same score, priority is given to the patient who has been waiting the longest.

While these priorities are designed to create a fairer process, they may have unintentionally led to certain injustices. These “counterbalances” must not be given too much importance if we are to maintain a fair system.

As a result, the Commission feels that certain measures should be implemented to ensure all patients awaiting a transplant are treated fairly, while avoiding, insofar as possible, the creation of categories that in turn create unfair situations.

As is the case with lungs, kidneys will be offered outside Québec only if there are no compatible recipients in Québec. Kidneys made available through programs outside Québec will be attributed according to Québec-Transplant’s attribution protocol. However, for reasons of safety, “kidneys that have accumulated over 48 hours of ischemia* or that will reach that threshold once transportation and tissue typing are taken into account, will be refused by the Québec-Transplant coordinator.

**Pancreas**

Pancreas attribution is a very unique process. The transplant patient undergoes an assessment process before part (islet of Langerhans*) or all of the organ is attributed. “The transplant surgeon evaluates whether the pancreas is suitable for transplantation of the entire organ.” Québec-Transplant also notes that “If the transplant patient’s condition does not allow transplantation of the organ, the pancreas will be offered to programs for isolation of the islets of Langerhans, with priority given to the Québec program before offering it outside the province.”

The many possibilities offered by a pancreas transplant are listed in order of priority. Combined kidney and pancreas transplants in the same patient take priority over the transplantation of a pancreas only and over isolation of the islets. In addition, transplantation of a pancreas only has priority over isolation of the islets.
Pancreases are attributed based on ABO compatibility and date of listing. However, Québec-Transplant notes that “a Group “O” pancreas will be attributed first to a Group “O” recipient, unless a recipient with another compatible blood group has been on the list longer (for at least 2 years).”

Organ distribution safety

The Commission believes that safety is of paramount importance when it comes to organ distribution. Organ harvesting, treatment, conservation, storage, and even distribution must all be strictly governed by the standards adopted by organizations in charge of organ distribution or imposed by government bodies. Québec-Transplant is currently reviewing its attribution criteria to take into account the latest Canadian standards for organ safety. Organ safety is directly related to the quality of the transplant. As a result, it has a direct impact on the success of transplantations and, by extension, on their efficiency. However, strict safety measures regarding acceptable ischemic times for organs may result in a decrease in the number of organs available for transplantation.

In its action plan on organ and tissue donations and transplantations in Québec, MSSS points to the potential security risk posed by disease transmission from organ or tissue donors to recipients. Despite the stringent standards and procedures in place to curtail this risk, the Department has brought to light a number of problem areas that the Commission would like to see corrected on a priority basis.

- There are no user-friendly tools to ensure the safety and rapid traceability of transplant organs (no effective integrated information system)
- Enrolment in the various quality control programs is voluntary. As a result, the degree of compliance with current safety directives varies considerably.
- There is no standardization of the protocols and procedures used by the various parties involved in organ and tissue donation and transplantation.
- There is no provincial transplant risk monitoring system or registry of donors and recipients that would make it possible to trace organs in a simple and effective manner.
- Establishments do not have the resources required to assess and mitigate the risks associated with hospitals when it comes to organ and tissue donation and transplantation.

Organ allocation: the challenge of striking a balance between fairness, effectiveness, and safety

Organ distribution encompasses the selection of transplant candidates and the distribution of organs. Organ distribution criteria are a crucial part of the process determining who will benefit from the rare resource that is transplant organs. The determining of these criteria and the weight they carry depend on the values held by society and those involved in the decision-making process.

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42. Ibid.
In its document on organ donation and transplantation, the Canadian Medical Association focuses on the two fundamental and conflicting values at the heart of the ethical dilemma that the Commission has faced throughout its period of reflection:

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 behavior45:

The Commission has refrained from making an unequivocal choice between organ distribution safety, fairness, and the effectiveness of transplantations (life expectancy and the degree of improvement of post-transplantation quality of life). Rather, through its comments, it has attempted to address the three values simultaneously with a view to striking a fair balance.

45. CANADIAN MEDICAL ASSOCIATION, Organ and tissue donation and transplantation [online], 2000. [http://www.cma.ca/index.cfm/ci_id/3207/l_id/1.htm]
Chapter 5
Other methods to alleviate the organ shortage

A number of strategies for alleviating the organ shortage have already been mentioned in this position statement, including basing cadaveric donations on cardiopulmonary arrest criteria or adopting a presumed consent model. However, other strategies also deserve the Commission’s attention. These highly diverse strategies raise ethical questions about social acceptability and feasibility. For example, even though there are no objections in principle to raising awareness about organ donation among hospital staff, the limits of this approach and questions on how to best broach the topic with ethnocultural communities are important issues. In contrast, organ commercialization is an ethically controversial strategy that has drawn increased media attention. Use of animal organs, or xenotransplantation, also raises ethical questions that those involved in organ donation and transplantation are unaccustomed to answering. And lastly, use of artificial organs brings up issues both philosophical—the robotization of human beings, for example—and concrete, such as the costs of this technology for society.

Raising awareness about organ donation: a promising avenue

Even though considered an effective means of increasing donor numbers, raising awareness about organ donation has attracted little attention in the abundant literature on the practice’s ethical dimensions. The vast majority of stakeholders and organizations consulted by the Commission concur that there is room for improvement in raising awareness among both hospital staff and the general public.

Raising awareness and training hospital staff

In the case of hospital staff, lack of awareness has serious consequences. According to Collège des médecins du Québec and MSSS, too many hospital employees lack proper training in organ donation for the process to run smoothly. To begin with, identification of potential donors and determination of death criteria (especially ways of verifying whether criteria are met) are problematic. In its report, the Transplant Committee of Québec’s Collège des Médecins affirms that “tertiary adult trauma centers house 4.5 times more potential donors (4.54%) than other Québec hospitals. Physicians at these facilities are generally well informed about organ donations, even though identification of potential donors can still be improved.” However, the College notes that “physicians in medical and coronary intensive care units are generally less attuned to identifying potential donors” than their colleagues in trauma intensive care units. For its part, MSSS notes in its action plan that:

Lack of knowledge about organ donation among certain healthcare professionals leads to deficiencies in identifying potential donors in Québec hospitals (organs are therefore lost because some brain dead patients are not identified as potential donors in the hospital setting).

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Collège des Médecins also points out that some physicians are still largely unfamiliar with brain death criteria: “Brain death diagnosis [or brain death criteria] is still apparently largely unknown to certain physicians, probably because it remains relatively infrequent in Québec hospitals during the course of a year.”

Moreover, according to a survey conducted for the Organ and Tissue Donation Promotion Committee at Centre Hospitalier Universitaire du Québec (CHUQ), nearly eight out of ten doctors described contact with donors’ families as rather difficult, whereas six out of ten said they had had no training in dealing with them. The survey also found that 53% of respondents would appreciate receiving training and information on the subject. In Sherbrooke, another survey of medical and surgical residents reached similar conclusions. According to survey authors, residents feel a need for better strategies in dealing with families. Even more worrisome, 77% of residents in medicine said they had little or no knowledge of the steps involved in the organ donation procedure.

The Commission would like to salute efforts by Québec-Transplant to address the lack of awareness and training among healthcare workers, especially by adding resource nurses at Québec hospitals. The Commission is confident that this initiative will enhance awareness, although it is conscious of the significant workload that resource nurses will have to bear.

The Commission believes that resource nurses must be given the resources they need to effectively and efficiently raise awareness.

In November 2004, the Kidney Foundation of Canada organized the third edition of its professional forum on organ and tissue donations. The forum provided healthcare professionals with an ideal opportunity to familiarize themselves with the various aspects of organ donation. The Commission believes that such initiatives must be encouraged and extended to enhance awareness among those involved with organ donations and transplantations.

However, further training is also required for healthcare professionals. The Commission therefore recommends as follows

**Recommendation No. 8:**

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

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5. Impact research, Étude sur la connaissance et les perceptions des médecins concernant le don d’organes et de tissus, Report prepared for the organ and tissue donation promotion committee at CHUQ, Québec City, June 19, 2003, pp. 37 and 59.
6. Ibid., p. 59
8. Ibid.
Raising public awareness

According to the most recent Léger Marketing poll on the topic, 73% of respondents were willing to donate organs.\(^9\) However, only 39% said they have taken steps to make their intentions known, either by signing the sticker on the back of their medical insurance card or by informing their family.\(^10\) In short, their intentions did not always translate into the steps required to make their wishes official.

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. In this regard, a Canada-wide study found that the population was ill informed about several aspects of organ donation and transplantation.\(^11\) In addition, numerous people consulted by the Commission mentioned the importance of promoting awareness among young people.

But to orchestrate awareness campaigns that take these observations into account, Québec will need to call upon an organization capable of assuming the task. Certain foundations and associations already perform awareness work, but as MESSS points out, “there is no comprehensive communication strategy in place to promote organ and tissue donation awareness among Quebécers (lack of public information can result in family members refusing to authorize potential donations).”\(^12\) In the recent past, INFO-DON, an umbrella group set up by various organizations involved in organ donation and transplantation, fulfilled this role.\(^13\) Established in the wake of the Gélineau Report\(^14\) in 1997, INFO-DON no longer has the mandate to conduct public awareness campaigns. Given the importance of raising the level of public awareness about organ donation, the Commission recommends as follows.

Recommendation No. 9:

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.

The organ shortage cuts across borders, cultures, and religions. However, for a variety of reasons, certain ethnocultural communities are more seriously affected than others. The incidence of high blood pressure, diabetes, heart disease, and kidney failure is higher among certain communities, which tend to be overrepresented on waiting lists. Several studies have already been conducted in an effort to better understand this situation and remedy perceived problems. Issues addressed include reasons for lower than average

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\(^10\) Ibid.


\(^12\) Ministère de la Santé et des Services Sociaux, op. cit., p. 15.


\(^14\) Comité sur les dons et les greffes d’organes et de tissus, Les dons et les greffes d’organes et de tissus au Québec, July 1997.
Organ Donation and Transplantation: Ethical Dilemmas Due to Shortage

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consent rates among certain communities, appropriate ways to broach the topic of organ donation with families, and the most effective awareness strategies for reaching these segments of the population.15

Awareness strategies cannot be readily targeted to cultural communities in general given the diversity of languages, beliefs, and concerns. The Canadian Council for Donation and Transplantation (CCDT) is preparing a position statement on this issue.17 The Commission feels that ongoing reflection on the issue is needed and should ideally lead to strategies for making organ donation and transplantation information more readily available to members of cultural communities. The Commission believes that they, like all citizens, must have ready access to this information.

Organ commercialization: Preventing the commodification of the human body

Organ commercialization refers to providing compensation for organ donation through various means or profiting financially from the sale of organs. There is a certain international consensus banning organ commercialization, be it in the form of compensation (to families of cadaveric donors) or remuneration (to living donors). However, recent proposals and the persistence of organ trafficking in certain regions have sparked renewed debate on the issue. The Commission believes that organ commercialization inevitably leads to commodification of the human body—i.e., any phenomenon that tends to treat the human body as merchandise, an object, or thing that can be purchased or traded.

Compensation and remuneration

The Commission defines compensation for organ donation as payment of a sum of money to the family of a cadaveric donor or a third party designated by the deceased, or as 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. A number of scenarios are being looked at, including tax credits, reimbursement of funeral expenses, and charitable donations. For the Commission, remuneration is even 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. Both of these forms of organ commercialization are generally condemned and banned by the international community.

Nonetheless, there are numerous arguments in favor of compensation and remuneration for organ donation. Certain observers claim that it is immoral to prohibit the poorest of the poor from selling their organs, especially since it may be the only way for them to

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16. On this subject, the initiative by Trilium Gift of Life is noteworthy. This organization, which coordinates organ donations and transplantations in Ontario, has produced an educational document available in English, French, Portuguese, Arab, Cantonese, Greek, Italian, and Mandarin. See http://www.giftoflife.on.ca/forefront/flash.cfm.

break the poverty cycle, or at least improve their standard of living. This argument is based on the conclusion that Western societies, incapable of helping poorer nations achieve a standard of living comparable with their own, have no right to ban the sale of organs, a practice that could provide an assist to the poorest individuals and their families, both in developing countries and the West. Others argue that if there is good reason to believe that the introduction of financial incentives would considerably increase the number of organs available for transplantation, thereby creating a moral obligation to make those incentives available.

Several scenarios have been put forth for introducing a form of organ commercialization for cadaveric donors. Some authors have suggested that responsibility for contacting families and harvesting organs be entrusted to private firms, which would in turn sell organs to organizations responsible for coordinating donations and transplantations. Motivated by profit, these firms would systematically approach families of potential cadaveric donors. Others, like the American Medical Association, have suggested compensating families of cadaveric donors by having potential donors sign contracts consenting to organ donation in exchange for financial compensation to their family or heirs in the event their organs were actually harvested upon their death. The idea is not only to encourage people to make a decision about donating their own organs, but to provide financial compensation as an incentive for the family to consent once the time comes. The AMA is also lobbying for pilot projects designed to determine whether financial incentives significantly increase organ donation rates. The ethical acceptability of this practice would be determined through a utilitarian approach using a cost/benefit analysis, as this passage illustrates:

Whether or not particular incentives are ethical depends upon the balance of resulting benefits and harms. These are currently unknown because they have never been studied.

Despite opposition from some AMA members and the National Kidney Foundation, a U.S. Congressman has introduced the notion of “financial incentive” into a bill to authorize pilot projects for testing such measures. The American Society of Transplant Surgeons also has a plan for reimbursing cadaveric donor funeral costs or making a donation to charity in the name of the donor. In this latter case, the goal is more to pay tribute to the donation, much as we decorate war veterans and fallen soldiers. In doing so, the altruistic act of organ donation is acknowledged as a gesture akin to heroism.

While proponents of certain forms of organ commercialization make their strongest case on utilitarian grounds, their adversaries counterattack on the basis of principle. First, they evoke the principle of noncommercialization of the human body (as affirmed in the

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23. Ibid., p. 748.
Organ Donation and Transplantation: Ethical Dilemmas Due to Shortage

Civil Code of Québec, the Québec Charter of Human Rights and Freedoms, and legislation in most other countries). Underlying this principle is the conviction that the human body is more just a commodity, and that economic reasoning does not apply for reasons of inherent human dignity. European ethics and law are very similar in tone:

Consequently, the principle of human dignity in organ transplantation militates against commercialisation of organs. There cannot be a liberal right to ownership of organs. To commercialise organs would lead to the treatment of some human beings as only a means, and it would necessarily result in a society with greater social inequality.26

Human autonomy is another principle at issue. Even though donors would be free to decide whether to sell their organs, the very possibility of doing so tends to commodify the human body. Treating the human body as an object that can be bought or sold does nothing to foster the full exercise of human autonomy.27 In addition, people from economically underprivileged communities also tend to be among the least educated and are often less well equipped to understand the health risks of organ donation, thereby limiting their ability to provide free and informed consent. By the same token, the possibility of payment puts pressure on people and undermines freedom of consent.28 In short, the best way to foster autonomy among living donors is to avoid financial incentives for organ donation.29

In addition, some see freely given donations as a guarantee of organ quality. The decline in the quality of blood products from paid donors, documented by Richard M. Titmuss,30 is revealing and may foreshadow what could happen in the organ transplantation field. Titmuss’ ideas are summarized by Philippe Steiner:

Given the establishment of certain blood banks in very low-income neighborhoods, blood collected from paid donors is of significantly lower quality than blood provided by volunteer donors. The reason is simple: volunteers have no reason to lie about their state of health and medical history; this is not the case for those giving blood for profit. Volunteer action goes better with trust than self-interest.31

Moreover, nothing guarantees that the number of cadaveric organ donations will increase with the introduction of financial compensation or remuneration. The main reasons for rejection are families who refuse to accept the death of potential donors and lack of instructions from potential donors.32 There is nothing to suggest that families will be more inclined to agree to organ donation because they benefit directly or indirectly from some form of compensation.

27. A comparison with slavery may be useful here: The slave, who is considered as a commodity or tradeable good, remains the property of his or her master, and therefore undergoes a significant decrease in autonomy.
Furthermore, although the major religions are officially in favor of organ donation and transplantation, they disapprove of organ commercialization. The position taken by the principal religions may help spur confidence in transplant medicine, but that confidence could be lost if commercial considerations are introduced.

For its part, the Transplantation Society has maintained its initial position that “Organs and tissues should be freely given without commercial consideration […]” As for the World Health Organization (WHO), it devotes four of its nine organ transplantation guidelines to the issue.

**World Health Organization guiding principles on the commercialization of organs for transplant purposes**

**Guiding Principle 5**
The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited.

**Guiding principle 6**
Advertising the need for or availability of organs, with a view to offering or seeking payment, should be prohibited.

**Guiding principle 7**
It should be prohibited for physicians and other health professionals to engage in organ transplantation procedures if they have reason to believe that the organs concerned have been the subject of commercial transactions.

**Guiding principle 8**
It should be prohibited for any person or facility involved in organ transplantation procedures to receive any payment that exceeds a justifiable fee for the services rendered.

The Council of Europe takes a similar stance in the Oviedo Convention: “The human body and its parts shall not, as such, give rise to financial gain.” In the Additional Protocol, on Transplantation of Organs and Tissues of Human Origin, the Council clearly sets out its prohibitions on organ commercialization (see inset).

33. Ibid., p. 222.
Organ Donation and Transplantation: Ethical Dilemmas Due to Shortage

Position Statement of the Commission de l’éthique de la science et de la technologie

The Commission believes that all forms of compensation or remuneration for donation are not only a violation of the law, but ethically unacceptable. Practices such as commercialization lead to commodification of the human body and run counter to human dignity. Commercialization limits the autonomy of potential donors and their families. In the Commission’s view, it is important to foster individual autonomy as this value—the very foundation of our North American legal and philosophical tradition—is not only a barrier to undue manipulation, coercion, and pressure, but also a precondition of democracy.

The Commission reaffirms that cadaveric and living donor donations must be based first and foremost on altruism. People donate organs for all kinds of reasons, but they do so freely, with no guarantee of receiving anything in return. Indeed, generosity and altruism are among the values cited by those consulted by the Commission as reasons for making organ donations. Introducing commercial transactions into the organ donation process would alter its underlying spirit of pure generosity. This conviction is the cornerstone of the British General Medical Council’s decision to ban organ commercialization:

1. Human organs should not be the subject of commercial transactions: any donation of organs must be made altruistically, as a gift.
2. Where human organs are bought or sold, transplantation will be governed by money rather than by the medical interests of the donors and recipients, with the vulnerable and the poor inevitably exposed to exploitation.

Article 21 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin

Chapter VI – Prohibition of financial gain

Article 21 – Prohibition of financial gain

1. The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.

The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations;
- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;
- compensation in case of undue damage resulting from the removal of organs or tissues from living persons.

2. Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited.

Council of Europe

The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations;
- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;
- compensation in case of undue damage resulting from the removal of organs or tissues from living persons.


38. See Appendix 1 for a summary of the consultation. For further details, see the Commission’s Rapport de consultation sur les enjeux éthiques du don et de la transplantation d’organes, which is available on the Commission Website: [http://www.ethique.gouv.qc.ca]

The Commission also believes that organ commercialization would have a negative impact on public trust in the organ donation and transplantation process, as well as the quality of harvested organs and the health of donors and recipients. Moreover, paying organ donors would likely lead to exploitation of economically disadvantaged members of society, both in Québec and around the globe. During the consultation, the Commission found that danger of encouraging less fortunate members of society to make living donations was one of the main risks of putting a price on human organs.

However, the Commission also found that opinions on the issue were divided among respondents to a survey it commissioned, with 48% somewhat or very favorable to financial compensation for families who consent to organ donation for a deceased family member. The Commission would like to point out that agreeing to compensation and remuneration for organ donation could open the door to organ imports from outside Canada and contribute to the exploitation of poorer populations in other regions. Potential donors among these populations are also at risk of consenting without being fully informed of the risks.

Organ trafficking

Numerous media reports indicate that organ trafficking is on the rise, which makes this phenomenon even more worrisome. Among the organs harvested worldwide every year, some are collected in circumstances where donor and recipient well-being takes second place to profit. Although the sale and purchase of organs is illegal in Canada and officially banned all over the world, trafficking rings are periodically broken up and news stories report on the harvest of living kidneys in countries like Pakistan, India, Mozambique, South Africa, Brazil, Lebanon, Iraq, Turkey, and Moldavia. Patients waiting for a transplant deal clandestinely through intermediaries to obtain a kidney. They are often generally prepared to spend tens of thousands of dollars on such adventures and to travel to the donor’s home country with a surgeon. This practice has given rise to the term "transplant tourism." At the other end of the chain, living donors receive only a small amount ($1,000 to $3,000) for a kidney. These kidneys are provided by economically vulnerable individuals who often view the sale of an organ as the fastest, most efficient way to obtain what for them is a substantial sum of money. However, this market has serious health consequences for many donors, especially in countries where they lack ready access to quality healthcare. As for recipients, a number of studies have shown that the quality of the grafts and the conditions in which transplant operations are conducted often lead to organ rejection.

40. See the appendix for an overview of Commission mini-survey results.
In a report on organ trafficking in Europe, the Parliamentary Assembly of the Council of Europe describes the situation as follows:

As a result of poverty, young people in some parts of eastern Europe have sold one of their kidneys for sums of US$2,500 to US$3,000, while recipients are said to pay between US$100,000 and US$200,000 per transplant. It is a matter of grave concern that following illegal transplants the donor’s state of health generally worsens in the medium term, due to the absence of any kind of medical follow-up, hard physical work, and an unhealthy lifestyle connected to inadequate nutrition and a high consumption of alcohol. Most illegal donors will thus be forced in time to live on dialysis treatment or await, in turn, a kidney transplant.

This situation raises a number of ethical questions: Should the poor provide for the health of the rich? Should the price of alleviating poverty be human health? Should poverty compromise human dignity and health? And in terms of medical ethics, should help to recipients be counterbalanced by neglect of, and harm to, donors?

The Parliamentary Assembly therefore disapproves of recent trends in some western European countries towards less restrictive laws, which would allow greater scope for unrelated living donation.44

The World Health Organization (WHO) has adopted a similar stance, noting that it is extremely difficult to document the traffic in organs or to prove or disprove rumors on the subject.45 WHO affirms that a ban on trafficking is not sufficient to halt the practice. The presumed cause remains poverty.

Great Britain has decided to add special provisions to its law on organ commercialization in order to reinforce the ban on organ trafficking. The law prohibits a series of activities, including supplying or seeking organs for remuneration and all advertising whose purpose could be the sale or purchase of organs. What sets the British law apart is the fact that these activities are banned even in cases where transplantation takes place outside the country.46

However, not all anti-trafficking legislation contains such barriers. The Council of Europe, which uncovered loopholes in the criminal codes of a number of European nations, has made a number of recommendations on the subject:

While prohibition of organ trafficking is legally established in member states, most countries still have legislative loopholes in this domain. Criminal responsibility in organ trade is rarely clearly specified in national Criminal Codes. Criminal responsibility should include brokers, intermediaries, hospital/nursing staff, and medical laboratory technicians involved in the illegal transplant procedure. Medical staff who encourage and provide information on “transplant tourism” should also be liable. The medical staff involved in follow-up care of patients who have purchased organs should be accountable if they fail to alert the health authorities.47

Given governments’ inability to prevent organ trafficking and provide disadvantaged populations with means other than organ donation to improve their living conditions, some authors have suggested regulating the market to better protect donors.48 Certain countries

have actually developed a legal framework that governs the sale of kidneys. In the Philippines, for example, a law limits the number of foreigners who can obtain kidneys.\textsuperscript{49}

The Commission reaffirms the unacceptability of organ trafficking under all circumstances.

**Xenotransplantation: the risks and potential of biotechnology**

In a society incapable of alleviating the organ shortage, research has turned to animals as a source of organs for transplantation in humans. Unthinkable not so long ago, xenotransplantation—i.e., the transplantation of living cells, tissue, or organs from one species to another—is now considered one possible avenue for producing organs, especially due to advances in biotechnology. In Canada, xenotransplantation has drawn the particular interest of Health Canada, which recently held a vast nation-wide consultation,\textsuperscript{50} the results of which are discussed later in the text.

Despite past failures, research in xenotransplantation has progressed (see Table 6) to the point where scientists no longer appear preoccupied about how to make it happen, but rather when clinical trials can begin.\textsuperscript{51}

There are benefits and concerns associated with xenotransplantation, which raises a whole new series of ethical issues related to organ donation and transplantation.

**Expected benefits of xenotransplantation**

The main benefit xenotransplantation is expected to provide is an adequate supply of organs for transplantation, thereby providing a means to end the organ shortage. In addition, xenotransplantation would take away the urgency of the organ transplantation process. Not only could donor organs be meticulously examined and evaluated for quality ahead of time, but all necessary steps could be taken to prepare the recipient in advance and minimize the risk of rejection. In the event of complications during these preliminary phases, healthcare providers would have all the time needed to correct the situation.


\textsuperscript{51} E. Ronchi, Advances in Transplantation Biotechnology and Animal to Human Organ Transplants (Xenotransplantation), Paris, OCDE, 1996.
In a 1999 position statement, France’s National Advisory Committee on Ethics (CCNE) noted that xenotransplantation would make it possible to eliminate “long waits during which patient health deteriorates, and emergency procedures on inadequately prepared individuals that are made necessary when an organ suddenly becomes available.”

Reducing waiting time for transplants is a significant benefit that would increase survival rates among patients waiting for organs and among recipients.

Many of the problems raised in the CCNE document would be resolved on their own if xenotransplantation became a normal and safe procedure. Issues related to cadaveric donors, living donors, organ distribution, and approaching families would disappear or become largely secondary. In the medium or long term, xenotransplantation could even hold out hope for an end to organ trafficking, which would no longer have any purpose.

Finally, the World Health Organization affirms that because of “the ability to plan and coordinate transplantations, xenotransplantation may become an economical alternative to human organ or tissue transplantation.”

### Concerns regarding xenotransplantation

A number of major concerns have so far prevented authorities and governments from pushing ahead with xenotransplantation. The risks for human health are very high and extend to all humans, adding to their scope and seriousness. Furthermore, the cost of xenotransplantation has yet to be evaluated.

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Human health risks

Organ grafts must improve patient quality of life or ensure patient survival. Transplant medicine has used allografts in humans to bring this about, but it is still too early to speak in these terms for xenotransplantation. Risks of rejection have been largely controlled for human organs, but the same cannot be said for organs of animal origin. Animal-to-human grafts of animal tissues have been performed for thirty years now. But tissues of animal origin are treated to behave as inert tissues to minimize the risk of rejection, the best example being pig heart valves. In the case of organ grafts, however, patients receive more than inert tissue, they receive a living organ that must perform all organ functions. Here lies the first challenge for human health: organs of animal origin may not perform all the same functions as their human equivalents. The liver is a patent example. Scientists still do not fully understand human liver function, which makes it doubly difficult to do comparisons with other animals. As CCNE indicates, liver xenotransplantation is still very much a utopian ideal.56 The Commission therefore believes that further research is necessary before any clinical trials are performed on humans. It also endorses Article 5 of the Recommendation of the Committee of Ministers of the Council of Europe to member states on xenotransplantation (see inset).

Article 5 – Xenotransplantation authorization

No xenotransplantation activity should be carried out in a member state unless authorization is given by a body officially recognized as competent for this purpose, in accordance with the provisions contained in the following two paragraphs:

1. Authorization for clinical xenotransplantation research should only be given if:
   a. pre-clinical research has demonstrated, in accordance with internationally accepted scientific standards, that
      i. in the light of current scientific knowledge it is highly probable that there is no risk, in particular of infection, for public health;
      ii. the potential level of efficacy and safety for the patient may justify the intervention having regard to the risks incurred;
   b. all substantive and procedural conditions generally applicable to clinical research are fulfilled.
2. Xenotransplantation should not be authorized other than in clinical research unless, on the basis of clinical data
   i. there is adequate evidence, in accordance with internationally accepted scientific standards, that no risks, in particular of infection, to the general population exist; and
   ii. the therapeutic benefit of the xenotransplantation has been established.

Recommendation of the Committee of Ministers to Member States of the Council of Europe57

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56. Comité consultatif national d’éthique, op. cit.
Primate organs: a logical, yet hard-to-defend choice

Xenotransplantations attempted on humans to date have not proven successful. Immunosuppressors currently available are incapable of preventing rejection.\(^{58}\) It seems logical to presume that the animals most closely related to humans from a genetic standpoint would be the best organ donors. And given their genetic similarities to humans, primates would seem the rational choice. However, despite the potential gains to be made with respect to organ compatibility, using primates as organ donors is highly problematic from a logistics and biosafety standpoint: it also raises a certain number of ethical issues that we will examine a little later on.

From a logistics standpoint, it seems hard to image raising primates in sufficient numbers to meet the needs of patients awaiting transplants. Primates neither reproduce very fast nor bear large numbers of offspring.\(^{59}\) Female baboons, for example, generally give birth to one baby per year.\(^{60}\)

From a biosafety standpoint, experts fear the risk of primate retrovirus\(^*\) activation in humans.\(^{61}\) Retroviruses could subsequently cause zoonotic diseases\(^*\). The AIDS virus and, to a lesser extent, bovine spongiform encephalopathy are two recent examples of animal-borne diseases being transmitted to humans.

This is why a number of bodies have already expressed their opposition to using nonhuman primates except in extraordinary circumstances. These include the Committee of Ministers in its recommendation on xenotransplantation to Council of Europe member states,\(^{62}\) Health Canada,\(^{63}\) the Nuffield Council on Bioethics,\(^{64}\) France’s National Advisory Committee on Ethics,\(^{65}\) and the Swiss Academy of Medical Sciences.\(^{66}\)

Pig organs: a major challenge

Using pigs as an organ source is a justifiable choice for logistic and biosafety reasons. Pigs offer several benefits, even though they are not completely without risk to human health. In its position statement on xenotransplantation, the Swiss Academy of Medical Sciences affirms that

The porcine species was chosen because the risk of infection is less than with the use of apes, because it is possible to breed pathogen-free animals, and also because the organs of the pig are about the same size as those of humans. On the other hand, up until now the pathogens specific to the pig have caused disease in humans only in exceptional cases.\(^{67}\)

Unlike primates, which mature slowly and are hard to raise in captivity, pigs grow large enough for organ harvesting within as little as six months.\(^{68}\) In addition, litters are large and pig breeding is a widespread and well-developed practice.

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61. This risk remains a factor even if other animal species are considered.
62. Council of Europe, Committee of Ministers, *op. cit*.
64. Nuffield Council on Bioethics, *op. cit*.
65. Comité consultatif national d’éthique, *op. cit*.
66. Swiss Academy of Medical Sciences, *op. cit*.
67. *Ibid*.
However, pigs raised to supply organs for transplantation to humans must be genetically modified, notably to make them more compatible with the human immune system. The goal of scientists is to render pig organ antigens inactive. These antigens are the principle target of human antibodies and the cause of organ rejection.  

*Risks that cross national borders*

Potential risk of infection resulting from xenotransplantation extends beyond national borders. This is why the decision to proceed with xenotransplantation cannot be made in isolation, but must reflect a degree of international consensus. There are two main reasons for this.

First, a country that proceeds in the absence of international consensus directly exposes its neighbors, and in fact all countries, to potentially enormous risk without their consent. Infectious diseases know no borders, and in the case of an undesirable event, all nations would be required to take action to prevent the spread of infection. Moreover, a country going it alone would undoubtedly attract xenotransplantation researchers from around the world, as well as patients waiting for transplants.

WHO has determined that even though xenotransplantation research and applications seem viable at the national level, certain complementary international initiatives are nonetheless necessary. WHO justifies its position on the grounds that the anticipated risks and benefits of xenotransplantation transcend national frontiers, which makes the practice an international public health issue. As for the Council of Europe, it affirms that “worldwide cooperation between states in this field is necessary.” In addition, it recommends that member states “cooperate in the setting-up of world-wide surveillance procedures and agreements” (see inset).

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**Article 31- International cooperation in medical research**

Member states should cooperate through international surveillance procedures and agreements. They should also take appropriate steps to facilitate the coordination of research in xenotransplantation in order to improve its efficacy and safety, to avoid unnecessary duplication and to minimize animal use and suffering.

**Article 32 – International cooperation in public health**

Every member state should communicate without delay to national public health authorities of other member states and other concerned states any events, in particular of infection, possibly related to a xenotransplantation which could compromise public health.

Recommendation of the Committee of Ministers to Member States of the Council of Europe

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69. E. Ronchi, op. cit.
71. Council of Europe, Committee of Ministers, op. cit.
72. Ibid.
73. Ibid.
Health Canada adopted a similar stance when it argued that the ethical issues raised by xenotransplantation, because they “cross national frontiers […] should also be discussed in international fora.” This July 1999 recommendation was implemented—at least at the national level—through the organization of a major pan-Canadian consultation on xenotransplantation.

In 2001, Health Canada provided funding to the Canadian Public Health Association for an independent consultation on the issue. The goal of the exercise was to determine whether Canada should proceed with xenotransplantation, and if so, under what conditions. The majority of respondents were opposed to Canada’s approving xenotransplantation, primarily due to the health risks involved. Participants also felt that other strategies for alleviating the organ shortage should be envisaged before resorting to xenotransplantation. Lastly, concerns over the ethical acceptability of xenotransplantation raised questions about the legitimacy of humans interfering in nature and using animals for their own benefit.

**Elevated costs**

Xenotransplantation-related activities are likely to be very expensive. The cost of transplant procedures themselves is unlikely to change, but the organs used will have to be purchased from firms that specialize in producing transgenic pigs raised specially for organ donation. Infrastructure requirements will undoubtedly demand major investments, which will be reflected in the cost of the organs produced. Significant sums will also be needed to monitor xenograft recipients. As Health Canada puts it,

> Life years gained by transplant recipients are difficult to enter into a strictly economic cost-benefit analysis. Savings in costs of dialysis, donor maintenance, and elective versus emergency surgery procedures would need to be offset against the costs of the breeding, maintenance, and surveillance of animal herds, patent and licensing fees, the cost of purchasing organs from commercial resource producing companies, and overall ongoing patient monitoring costs.

The Organization for Economic Cooperation and Development (OECD) concurs and concedes that use of xenotransplants as a bridge to organ grafts of human origin would be a very costly solution.

**Ethical issues**

Xenotransplantation raises ethical issues that are relatively new with respect to organ donation and transplantation, including animal welfare and the patentability of life. Other issues such as consent, biosafety, and the social acceptability of new medical practices may not be completely new, but do take on a different dimension.
Social acceptance of xenotransplantation

It is difficult to anticipate how the population will react to xenotransplantation. For the moment, the consultation held in Canada provides a glimpse of the public’s reticence regarding animal-to-human transplants. If xenotransplantation becomes safe, its social acceptance will probably vary from one society and culture to the next. The use of animals—and genetically modified ones at that—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 families and friends. In the case of recipients, the possibility of obtaining a transplant that allows them to live better and longer is likely to outweigh these other considerations. But the Commission is still concerned about possible stigmatization, and even discrimination, against xenograft recipients. Moreover, 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.

Use of pigs does not appear to give rise to the intense misgivings that primates, our closest cousins, do. Nonetheless, “there may also be religious and cultural concerns about the use of pigs for transplantation purposes, and these must also be respected.”82 In some cultures, pork is a forbidden food because pigs are considered impure. As for the use of transgenic pigs, the Commission has already dealt with this topic from the perspective of cultural and religious representations in an earlier position statement on genetically modified organisms.83

The Commission agrees with the WHO recommendation that scientists, healthcare professionals and other stakeholders such as religious leaders and the media must play an important role in informing the population and fostering debate on the safety, effectiveness, and acceptability of xenotransplantation.84 Not only is it important to educate the population about the issues associated with xenotransplantation, but also to provide it with the tools to make an informed decision on the subject. To this end, the recommendation of the Committee of Ministers to the member states of the Council of Europe regarding xenotransplantation called for “appropriate public discussions” (see inset).

Article 30 – Public debate

In accordance with the principles stated in Article 28 of the Convention on Human Rights and Biomedicine, member states should take active steps to ensure that the fundamental questions raised by xenotransplantation are the subject of appropriate public discussion, particularly in light of relevant medical, psychological, cultural, ethical, legal, social, and economic implications.

Recommendation of the Committee of Ministers to Member States of the Council of Europe85

83. Commission de l’ethique de la science et de la technologie, Pour une gestion éthique des OGM, Québec, 2003, pp. 74-80.
85. Council of Europe, Committee of Ministers, op. cit.
Consent

Consent to clinical xenograft trials or xenografts themselves not only involves the consenting person, but also their family, loved ones, and, ultimately, society as a whole. In much the same way as providing information to a genetic database, the risks associated with xenotransplantation—notably the transmission of retroviruses and zoonotic disease—can affect the consenting person as well as everyone around them.

Assessing actual risks and benefits can be very difficult so long as clinical trials are not held on humans. At the same time, potential trial participants are likely to find it hard to make an informed decision given the incomplete state of current information on the risks involved. This led the Nuffield Council on Bioethics to make the following recommendation in its position statement:

That the consent of patients to participation in xenotransplantation trials is sought by appropriately trained professionals who are independent of the xenotransplantation team.

The information given to prospective recipients should include an estimation of likely success, attendant risks, and subsequent quality of life.

To ensure the collection of the maximum amount of information on recipient quality of life and life expectancy and minimize the risk of infection or other undesirable events, consent to xenotransplantation should include a whole series of obligations for the organ recipient. These obligations range from long-term medical monitoring and agreement to practice safe sex to quarantine in the event of a contagious or hitherto unknown disease.

Medical monitoring and the ensuing data collection also raise privacy protection issues.

To protect minors and adults unable to provide informed consent, a certain consensus has developed to reject their participation in xenograft clinical trials or xenografts themselves unless certain specific conditions are met to ensure their protection.

Animal welfare

Xenotransplantation raises a number of ethical issues related to animal welfare, including the instrumentalization, patentability, treatment and commercialization of animals. These issues are much too complex to be thoroughly dealt with in this position statement.

The concern with animal welfare is, in itself, relatively recent. Population interest in nature conservation in general has coincided with the emergence of the environmental and animal rights movements, and continues to grow steadily. 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.

88. Ibid., p. 88.
89. For proposed restrictions and obligations, see Health Canada, Proposed Canadian Standard for Xenotransplantation, July 1999, p. 7; Council of Europe, Committee of Ministers, June 19, 2003, op. cit.
90. Health Canada, Proposed Canadian Standard for Xenotransplantation, July 1999, pp. 6-7; Council of Europe, Committee of Ministers, op. cit.; Swedish Committee on Xenotransplantation, From One Species to Another – Transplantation from Animals to Humans, Swedish Government Official Report No. 1999, Stockholm, 1999, p. 120
However, some observers argue that using animals for the benefit of human health is not fundamentally bad. It is possible to use animals for xenotransplantation while at the same time respecting certain basic, widely recognized animal rights, including the right to be protected from suffering or unnecessary sacrifice.\textsuperscript{94}

Xenotransplantation would lead to an instrumentalization of nature, and especially of animal organ donors. By instrumentalization, the Commission means considering nature as a means of serving human interests. However, this anthropocentric\textsuperscript{*} view of nature requires that in exchange, animals such as those used for experimental purposes be treated with fundamental decency. Every effort should be made to minimize the suffering of these animals, and special attention must be paid to use only the number of animals needed.\textsuperscript{95} There is a certain international consensus to the effect that animal organ donors be treated with respect.\textsuperscript{96}

**Biosafety**

The Commission views biosafety as 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 public—and kept to a level deemed acceptable. It thereby recommends as follows:

**Recommendation No. 10:**

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.

From a legal perspective, the Commission considers that developing a legislative framework for xenotransplantation is a monumental, but achievable task. The national and international dimensions of regulation need to be overcome to ensure public welfare and safety. Regulators will need to address the designation of xenotransplantation centers, patient monitoring and animal breeding criteria, and the management of undesirable events, as well as prioritize the harmonization of national and international regulations.

**Artificial organs: a promising yet costly alternative**

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. Not only are there numerous obstacles to overcome, but the technology could also be very expensive for eventual users.

The Commission nonetheless chose to provide a quick overview of current artificial organ technology and examine the main ethical issues this technology raises. However, it did not explore the area of bioengineered organs, which may one day be produced from stem cells. That is a another debate entirely.

\textsuperscript{94} Ibid., p. 64.

\textsuperscript{95} M. Sykes, A. D’Apice and M. Sandrin, \textit{op. cit.}, pp. 194-203.

Heart

Currently, there are a variety of cardiac assist systems available, including circulatory assist systems, prosthetic valves, and pacemakers. These systems are considered as a bridge to heart transplant rather than permanent solutions.

Circulatory assist systems are used on “patients in shock who have suffered a heart attack or heart inflammation leading to poor perfusion of organs and coronary arteries.” They “assist the failed ventricle* by taking over ventricular function.” There are two types of circulatory assist systems: internal and external. Among internal systems, the recently developed Jarvik 2000 has obtained very good results.

Prosthetic valves can be mechanical or biological. Although they are tissues rather than organs, the Commission decided to include them here, in part because they can help patients awaiting transplant to survive. Mechanical valves are used to replace defective valves. Their main disadvantage is that they require the use of anticoagulants* to prevent blood clots that could obstruct the valves. Some of them also need to be replaced after approximately ten years. Biological prosthetic valves may be of either human or animal origin. The first transplants were of human origin, but problems with preserving valves harvested from deceased donors and matching recipient size requirements led to the development of prosthetic valves of animal origin, or bioprostheses. Bioprostheses are sterilized and chemically treated against immune reactions to become like inert substances. Unlike mechanical valves, they do not require anticoagulants. Most have a life expectancy nearing 12 years. “Bioprostheses are primarily prescribed for patients 75 and over, people incapable of tolerating anticoagulants, and women of child-bearing age.” Recent improvements in the conservation of biological valves of human origin have led to better clinical results than with bioprostheses.

Pacemakers “send an electrical signal to the heart muscle (myocardium) to ensure a regular heartbeat.” Pacemaker installation has its inconveniences. Once every six or twelve months, pacemaker wearers have to go in for a battery and heart data check. Furthermore, patients must be cautious around devices emitting electromagnetic waves.

Pancreas

The only technology currently available is a subcutaneous insulin* infusion pump. This pump regulates the flow of insulin based on blood sugar levels, which are constantly measured. It comes in portable and implantable versions. Research is also underway to develop a semi-artificial pancreas. Islet of Langerhans cells are placed in a plastic capsule, which is then connected to the blood stream.

98. Ibid.
101. Ibid.
102. Ibid.
Kidneys

The basic idea behind the artificial kidney—or hemodialysis—is to remove the toxins a natural kidney normally removes from the blood. A dialysis machine is too big and complex to be used outside a hospital setting. Even though patients are not permanently connected to the machine, they undergo from two to four 3-hour treatments per week, which severely limits their independence and quality of life. There is one other possibility, although it does not guarantee better results. Peritoneal dialysis allows patients to undergo treatment at home. This method involves using the peritoneum (the membrane lining the abdominal cavity) as a filter. It gives patients more freedom, but requires more discipline on their part, because they have to do their own treatments.

Liver

The liver is an organ whose exact workings are still rather poorly understood. Key liver functions include metabolizing substances such as proteins, carbohydrates, and lipids, as well as secreting bile, which helps the body digest food and eliminate toxins from the blood. Bio-artificial livers currently in use to provide temporary liver support only provide one function: detoxification*. Research into the development of an artificial liver is continuing, however, notably in France[104] and California.[105]

Ethical issues

The two ethical issues that the Commission decided to address do not cover the full scope of the impact the introduction of artificial organs may have. However, they are probably the two most pressing issues, and encompass the central ethical questions that are raised.

Distribution of resources

As mentioned in Chapter 1, cost becomes an ethical issue especially when society has to make choices about resource distribution.[106] Distribution poses ethical challenges no matter what kind of healthcare system is in place, but even more so in a universal healthcare system like Québec's. The Commission has a number of concerns about the introduction of a technology as costly as artificial organs in this type of system, notably with regard to access. It is not easy to determine whether the government or patients awaiting transplants should pay for this kind of technology, or who will have access to it. It is equally difficult to determine the extent to which the government should fund preventive campaigns rather than focusing on curative medicine, which includes transplant medicine. The debate is on, and the decisions have yet to be made.

The Commission believes it is crucial to stress that universal access to quality healthcare is a given in Québec society that must be preserved. However, it believes that other avenues need to be fully explored before developing fully self-contained artificial organs. Current technologies, although costly, keep transplant patients alive while waiting for surgery, or at least extend their life expectancy—a situation that comes into direct conflict with transplant medicine's goal of achieving a more effective allocation of resources in a context of shortage.

104. Ibid.
In addition, making artificial organ technology available to a significant proportion, or even the totality of patients awaiting transplant surgery, would be staggeringly expensive, and probably too high for Québec society to assume. **Therefore, less costly and perhaps more effective strategies must be examined, notably raising awareness among the general population and healthcare professionals and implementing prevention campaigns to reduce the incidence of diseases that leave people in need of an organ transplant.**

**Robotization of the human body**

The implantation of artificial organs in the human body would have been considered as science fiction not so long ago. The idea of artificial organ transplants has major ethical and philosophical implications. **Although patients whose survival depends on an organ transplant are unlikely to take this aspect into account in their decision, the Commission believes it is important to reflect upon it nonetheless.**

The Commission wonders how artificial organ recipients are likely to see themselves. Accepting an organ from a human donor can be psychologically trying for certain recipients. What would the consequences be if the organ were a machine? Does the development of artificial organs contribute to the robotization of human beings? If so, what will the psychological and philosophical repercussions be? **The Commission believes it would be prudent to think about these issues before proceeding too far in the development of artificial organs.**
Conclusion

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, dilemmas that the Commission had ample opportunity to appreciate over the course of its deliberations and consultations, and that it took into consideration in the process. It is clear that the emotional climate surrounding organ donation and transplantation amplifies the seriousness of the ethical dilemmas it raises.

Before addressing these issues, the Commission had to first question the fundamental ethical acceptability of organ donation. 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 on the one hand and the ethical acceptability of their applications on the other. It therefore undertook its deliberations on the premise that organ donation is ethically acceptable.

To gain a clearer understanding of the subject before examining the ethical challenges of each of its various aspects, the Commission began by looking at the overall context of organ donation and transplantation. This overview brought to light a number of observations: While transplant medicine is a relatively new field, it is well attuned to the latest scientific and technological advances; the practice of organ donation and transplantation is well regulated by a series of legal and ethical standards; society’s choices in the allocation of healthcare resources have a capital ethical dimension that requires an overarching vision; and the key players in the field of organ donation and transplantation are hard-working and committed, but face a serious shortage of human, material, and financial resources. However, the main observation on which the Commission based all its ethical deliberations was the following: Far more patients are awaiting a transplant than there are organs available, and people are dying, sometimes after a long wait, without ever receiving the organ they hoped for. While hardly encouraging, it should be noted that this same situation prevails throughout the world.

The technical aspects of organ donation raise a number of questions, which the Commission addressed while making the distinction between brain death criteria (BDC) cadaveric donations and living donations. In addition to these two donation categories, it also examined the issue of cardiac death or non-heart-beating organ donors. While certain ethical questions, including transparency, anonymity, and safety apply to various types of organ donation, each question was examined individually. This allowed the Commission to observe and explicitly confirm the importance of such values as beneficence, authenticity, and the free and generous nature of the donation, as well as autonomy and human dignity.
With regard to BDC cadaveric donations, the Commission reiterated the importance of transparency in the care provided to patients and donors and in the organ harvesting process, as well as organ donor anonymity. On this matter, the Commission saw fit to make a recommendation to the effect that Québec-Transplant and physicians involved in the organ donation and transplantation process maintain the current donor anonymity policy, but that they consider requests from the organ donor’s family or the recipient(s) to meet and, if both parties agree, clearly inform the parties of the risks involved and ask them to sign a consent form to this effect. Furthermore, the Commission recommends that such meetings be followed up on to assess their value.

On the matter of living donations, the Commission believes that it is essential to promote free consent, inform donors of the health risks involved, and undertake further research on these risks. To this effect, it recommends that transplant centers, in cooperation with Québec-Transplant, recognize the value of living organ donation for kidney transplants and develop good practice guidelines in this regard. In addition, it recommends that transplant teams 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. Furthermore, the Commission believes that it is unacceptable for an employer to take discriminatory measures against employees who donate an organ. Accordingly, it recommends that the Québec government ensure that living donors at no time suffer discrimination as a result of their donation or its aftereffects. The Commission also feels that reimbursing living donors for expenses incurred as part of the donation process is an acceptable practice that can go a ways toward alleviating an irritating, if not unfair situation. It therefore recommends that the government explore this possibility.

The Commission also examined the controversial matter of cardiac death or non-heart-beating organ donation. It believes this avenue could be explored, but with caution, as it raises many ethical questions. The Commission has made three recommendations—one general and two specific—with a view to taking into account the ethical challenges of transparency and trust, dignity, and respect for the donor, as well as respect for the life of the donor and preservation of the organs to be harvested.

The Commission then looked at the issue of consent and how to raise the subject with families. After examining two main consent models (explicit and presumed) and two ways of implementing them (mandated choice and creation of a registry), it concluded that the explicit consent model currently used in Québec works very well and is more in keeping with the notion of donation as a voluntary and generous gesture.

In examining the matter of how to approach families, the Commission focused on three fundamental values: respect, autonomy, and trust. While these aren’t the only values that come into play, they are the three main ones that should guide healthcare providers in their work. Recognizing a family’s grief and maintaining as neutral a tone as possible when discussing the subject of organ donation are ways to show respect toward the family. Autonomy is required for family members to reach informed decisions; however, it entails providing families with all the information they need on the patient’s state of health and on such medical concepts as brain death. Trust is created when the first two values are met. Showing respect for families and providing them with the means to make free and informed decisions helps forge a bond of trust between healthcare professionals and the family. In this regard, the Commission wishes to commend Québec-Transplant for its initiative in training special resource nurses, whose tasks include providing support to families of patients who suffer brain death.
The Commission also looked into the matter of organ distribution. Given the current organ shortage, the two components of the organ distribution process—selecting transplant candidates for the waiting list and attributing organs—take on considerable importance. It therefore comes as no surprise that tensions arise and ethical questions are raised. The Commission has taken a stand and made a recommendation to strike a balance between fairness, efficiency, and safety. These three values often come into conflict when decisions are made about who receives a transplant organ. However, rather than seeking to favor one value over another, the Commission has attempted to identify compromises that are more likely to strike a balance.

After examining the issues of living donation, presumed consent, and non-heart-beating donation, the Commission looked into other strategies to alleviate the organ shortage. These include awareness campaigns, commercialization, xenotransplantation, and artificial organs.

Québec-Transplant and the Kidney Foundation of Canada, among others, have made considerable efforts to raise awareness among and provide training to healthcare professionals. Nonetheless, the Commission recommends that education officials ensure that the appropriate college and university study programs devote teaching time to organ donation and transplantation and their ethical dimensions, and that healthcare professionals attain a truly broad understanding of organ donation and transplantation (ethical issues, death determination criteria, identifying potential donors, donor life support, how to approach families, mourning, ethnocultural communities, etc.) and organize more professional training activities in this regard to address the deficiencies that were brought to its attention over the course of its consultations. The Commission’s consultations also led it to conclude that efforts in this area should stress the social value of transplants and promote greater public awareness of the benefits of transplants, and it has thus recommended that Québec-Transplant, in cooperation with other organizations in the field, be given special responsibility (and the necessary funding) to carry out public awareness initiatives.

Organ commercialization is a highly controversial issue, which is why the Commission sought out arguments for and against the practice before taking a stand. It is opposed to compensation, remuneration, and organ trafficking, primarily because these forms of organ commercialization lead to the commodification of the human body. Every human body has intrinsic dignity that makes it unacceptable from an ethical point of view to consider organs as mere objects of trade. Moreover, the Commission believes that organ commercialization could have a harmful effect on public trust in the organ donation and transplantation process, on the quality of organs harvested, and on donor and recipient health. It therefore believes that organ donation must be driven by selfless motives.

While xenotransplantation (transplantation of animal organs into humans) seems to hold out considerable promise, it also raises significant concerns on which the Commission focused its attention, including human health risks and the risk of propagation of animal-origin infectious diseases, as well as the high costs involved in acquiring organs and monitoring xenograft patients. Although the Commission only touched on xenotransplantation briefly, it looked at a number of ethical dilemmas, such as social acceptance, consent of candidates, animal welfare, and biosafety—all issues for which difficult decisions may soon have to be made. Given the risks this practice poses to human health, the Commission recommends maintaining the moratorium on xenotransplantation and any related clinical trials until conclusive scientific results on
animal models have been obtained. Furthermore, it feels that there should be more information made available to the public, and that clear national and international guidelines should be set before moving ahead.

The Commission noted that there is much work to be done before complete, self-sufficient, and implantable artificial organs are developed for transplant in humans. Moreover, if this practice does prove promising, it will raise major ethical questions due to the resources required and the high cost of artificial organs, at least as the current situation stands. The Commission also questioned whether the development of artificial organs would lead to the robotization of the human body in symbolic terms, an issue it feels raises major ethical questions.

The Commission undertook its deliberations with a great deal of interest and respect. It hopes it has succeeded in shedding light on the ethical complexity of the subject and striking a fair balance in its assessment and hierarchization of the values at play. Lastly, it hopes that its deliberations will help provide guidance to political and institutional decision makers.
Glossary*

ALLOGRAFT: The transfer of cells, tissue, or an organ between two individuals of the same species, but genetically different

ANTHROPOCENTRIC: The view or belief that humans are at the center of the universe and the good of humanity comes above all else

ANTIBODY: A protein produced in the body in response to invasion by an antigen and binding to the antigen to neutralize it

ANTICOAGULANT: A substance that prevents, delays, or inhibits blood from clotting

ANTIGEN: Any substance that can trigger an immune response by stimulating the production of antibodies

AUTOGRAFT: The transfer of cells, tissue, or an organ from one place to another within the same individual

BLOOD GROUPS: A series of antigenic properties of the blood (the source of red blood cells) used to classify individuals and control blood transfusion between compatible donors and recipients. There are some 20 blood group systems, but the most common are the four-group ABO system—A, B, O (universal donor), and AB (universal recipient)—and the Rhesus system (positive and negative).

CANNULA: A hollow tube, which can be rigid or flexible and straight, curved, or angled, used to allow air or fluid to enter a natural cavity or duct or a surgically opened vessel or channel

COLD ISCHEMIA: The condition of a tissue or organ, after harvesting, that is not supplied with blood and is refrigerated at 4° C

CROSSMATCH: A test in which the donor’s and recipient’s blood is mixed together to detect any cytotoxic antibodies that could cause the body to reject a grafted kidney. A positive crossmatch indicates incompatibility between the donor (living or dead) and the recipient.

DETOXIFICATION: A biochemical process in the liver, adrenals, lungs, or kidneys that neutralizes the toxins in a substance introduced into the body or resulting from its normal or pathological processes

EISENMENGER SYNDROME: A congenital heart defect causing hemodynamic disturbances (poor blood circulation) and cyanosis (insufficient tissue oxygenation) associated with elevated blood pressure in the lungs due to insufficient arterial blood flow to the pulmonary arteries

* Definitions are based on the following sources: Le Grand dictionnaire terminologique, the Vulgaris-Médical website (http://vulgaris-medical.com), and the patient manual Living with Kidney Disease by the Kidney Foundation of Canada.
EXCLUSION CRITERIA: A condition that automatically renders a candidate ineligible

FEMORAL ARTERY: A blood vessel in the thigh that carries blood from the heart to the rest of the body

GRAFT: Cells, tissue, or an organ transferred from one place to another within the same individual or from one individual to another

HEART-LUNG BLOCK: A heart and set of lungs transplanted together to a patient awaiting a transplant

HEMODYNAMIC: The mechanics of blood circulation in the cardiovascular system

HLA (HUMAN LEUKOCYTE ANTIGEN): Immune system molecules responsible for graft rejection. The system includes the four genes HLA–A, B, C, and D on chromosome 6. The A, B, and C genes encode for very specific proteins found on the membranes of all cells in the body and serve primarily for self-recognition. The HLA system is extremely valuable not only in selecting grafts, but also in identifying susceptibility to certain diseases.

IMMUNE SYSTEM: The body's lines of defense against foreign invaders

IMMUNOLOGY: A branch of biology that studies normal and pathological immune responses

IMMUNOSUPPRESSANT: Any substance that reduces or suppresses immune responses

INSULIN: A hormone produced by the islets of Langerhans in the pancreas

INTENSIVIST: Physician at a hospital intensive care unit

ISLETS OF LANGERHANS: Irregularly shaped gray or yellowish patches in the pancreatic tissue that secrete insulin

LEUKOCYTE: A mature, nucleated blood cell in the blood stream that defends the organism against infection

LIVING WILL: A written document indicating an individual’s wishes regarding end-of-life care in the event he or she is unable to communicate

LYMPHOCYTE: Mononuclear leukocyte in the blood, lymph, bone marrow, and lymphoid organs

MACROPHAGE: A cell derived from a monocyte that has moved from the blood stream into a tissue, with an important role in immunity, notably through its ability to destroy microbes

NEOPLASIA: Abnormal growth of new tissue resembling the normal adult or embryonic tissue from which it developed, persisting and growing after the stimuli that initiated it have ceased, and defying the biological rules of growth and cellular differentiation. Synonym: tumor

PERFUSION: Slow, continuous intravenous injection of considerable amounts of a solution used to cool organs
POTENTIAL DONOR: Any patient intubated and on assisted ventilation for whom brain death is suspected, projected, or declared and who does not meet any exclusion criteria or show any cardiovascular instability in blood circulation

REFERRAL: Any call received by Québec-Transplant identifying an organ or tissue donor

REGENERATION: The physiological renewal of a damaged organ

REJECTION: Immune process in which the recipient’s body fights against a graft or transplant from a donor with a different genetic makeup

RETROVIRUS: An RNA virus that uses the reverse transcriptase enzyme to copy its RNA into DNA, then enter and integrate into the genome of the host cell

TISSUE INCOMPATIBILITY: Key differences in a donor’s and recipient’s tissues preventing a successful graft

TYROSINEMIA: An abnormally elevated blood tyrosine levels in newborns due to enzymatic immaturity

VENTRICLE: A small cavity. Especially the two lower chambers of the heart or the four cavities in the brain

WARM ISCHEMIA: The condition of a tissue or organ, after harvesting, that is not supplied with blood and is not yet refrigerated

XENOTRANSPLANTATION OR XENOGRAFT: Transfer of cells, tissue, or an organ between two individuals of different species

ZOOONOTIC DISEASE OR ZOONOSIS: Infectious or parasitic infection in domestic or nondomestic vertebrate animals that can be transmitted to humans in natural conditions, or vice versa


* Unless otherwise indicated, all URLs were accessible October 25, 2004, either directly or through site archives.


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Position Statement of the Commission de l’éthique de la science et de la technologie


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Kidney Foundation of Canada, Québec Branch. [http://www.reinquebec.ca/ang/index_en.htm]


Organ Procurement and Transplantation Network. [http://www.optn.org/]


Organ Donation and Transplantation: Ethical Dilemmas Due to Shortage

Position Statement of the Commission de l’éthique de la science et de la technologie


Trilium Gift of Life. [http://www.giftoflife.on.ca/forefront/flash.cfm]


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 paper\(^1\) led the Commission to isolate 33 ethical questions\(^2\) 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).

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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 results**

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.

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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 Statmédiamedia Survey in Spring 2004 (Jolicoeur et Associés)

CEST was invited by the firm Jolicoeur et Associés to participate in the spring 2004 Statmédiamedia survey, a phone survey of 1,935 people^4 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 breakdown^5:

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?

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<td>Somewhat in favor</td>
<td>31%</td>
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<tr>
<td>Somewhat opposed</td>
<td>24%</td>
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<tr>
<td>Strongly opposed</td>
<td>29%</td>
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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 Quebeckers 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?

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<td>Strongly in favor</td>
<td>38%</td>
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<tr>
<td>Somewhat in favor</td>
<td>29%</td>
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<tr>
<td>Somewhat opposed</td>
<td>15%</td>
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<td>Strongly opposed</td>
<td>18%</td>
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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?

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<tr>
<td>Somewhat in favor</td>
<td>25%</td>
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<tr>
<td>Somewhat opposed</td>
<td>18%</td>
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<tr>
<td>Strongly opposed</td>
<td>27%</td>
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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)?

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<tr>
<td>Strongly in favor</td>
<td>50%</td>
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<tr>
<td>Somewhat in favor</td>
<td>41%</td>
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<tr>
<td>Somewhat opposed</td>
<td>6%</td>
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<tr>
<td>Strongly opposed</td>
<td>3%</td>
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</table>

This support diverges very little by sociodemographic profile.
## Appendix 2

### Québec Statistics*

### Table I

<table>
<thead>
<tr>
<th>Years</th>
<th>Total number of referrals</th>
<th>Referrals refused</th>
<th>Referrals accepted</th>
<th>Rejected donors</th>
<th>Accepted donors</th>
<th>Living kidney donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>257</td>
<td>124</td>
<td>133</td>
<td>16</td>
<td>117</td>
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</tr>
<tr>
<td>1996</td>
<td>258</td>
<td>121</td>
<td>137</td>
<td>24</td>
<td>113</td>
<td>14</td>
</tr>
<tr>
<td>1997</td>
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<td>152</td>
<td>114</td>
<td>18</td>
<td>96</td>
<td>16</td>
</tr>
<tr>
<td>1998</td>
<td>273</td>
<td>129</td>
<td>144</td>
<td>24</td>
<td>120</td>
<td>30</td>
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<td>193</td>
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<td>31</td>
</tr>
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<td>2000</td>
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<td>158</td>
<td>158</td>
<td>23</td>
<td>135</td>
<td>31</td>
</tr>
<tr>
<td>2001</td>
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<td>128</td>
<td>159</td>
<td>23</td>
<td>136</td>
<td>46</td>
</tr>
<tr>
<td>2002</td>
<td>293</td>
<td>139</td>
<td>155</td>
<td>27</td>
<td>127</td>
<td>45</td>
</tr>
<tr>
<td>2003</td>
<td>395</td>
<td>216</td>
<td>169</td>
<td>27</td>
<td>142</td>
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</table>

### Table II

<table>
<thead>
<tr>
<th>Years</th>
<th>Kidney</th>
<th>Kidney/pancreas</th>
<th>Pancreas</th>
<th>Liver</th>
<th>Heart</th>
<th>Heart/lungs</th>
<th>Lungs</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>1995</td>
<td>450</td>
<td>8</td>
<td>2</td>
<td>30</td>
<td>27</td>
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<td>27</td>
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</tr>
<tr>
<td>1996</td>
<td>471</td>
<td>16</td>
<td>5</td>
<td>32</td>
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<td>28</td>
<td>577</td>
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<tr>
<td>1997</td>
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<td>8</td>
<td>42</td>
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<td>3</td>
<td>29</td>
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</tr>
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<td>1998</td>
<td>486</td>
<td>37</td>
<td>6</td>
<td>38</td>
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<td>27</td>
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</tr>
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<td>1999</td>
<td>593</td>
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<td>15</td>
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<td>28</td>
<td>3</td>
<td>34</td>
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<td>2000</td>
<td>637</td>
<td>47</td>
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<td>46</td>
<td>17</td>
<td>4</td>
<td>35</td>
<td>815</td>
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<td>67</td>
<td>31</td>
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<td>28</td>
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</tr>
<tr>
<td>2002</td>
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<td>28</td>
<td>90</td>
<td>36</td>
<td>4</td>
<td>39</td>
<td>925(^1)</td>
</tr>
<tr>
<td>2003</td>
<td>638</td>
<td>32</td>
<td>18</td>
<td>91(^2)</td>
<td>27</td>
<td>6</td>
<td>48</td>
<td>860</td>
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1. 1 recipient awaiting an intestine.
2. 4 recipients awaiting a liver-kidney transplant.
Table III
Number of Transplants

<table>
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<tr>
<th>Years</th>
<th>Kidney</th>
<th>Kidney/pancreas</th>
<th>Pancreas</th>
<th>Liver</th>
<th>Heart</th>
<th>Heart/lungs</th>
<th>Lungs</th>
<th>Kidney (living)</th>
<th>Total</th>
</tr>
</thead>
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<tr>
<td>1995</td>
<td>199</td>
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<td>1</td>
<td>87</td>
<td>51</td>
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<tr>
<td>1996</td>
<td>184</td>
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<td>1997</td>
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<td>3</td>
<td>86</td>
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<td>22</td>
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<tr>
<td>1998</td>
<td>170</td>
<td>3</td>
<td>8</td>
<td>90</td>
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<td>17</td>
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<td>356</td>
</tr>
<tr>
<td>1999</td>
<td>201</td>
<td>7</td>
<td>13</td>
<td>112</td>
<td>39</td>
<td>2</td>
<td>22</td>
<td>31</td>
<td>427</td>
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<tr>
<td>2000</td>
<td>217</td>
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<td>17</td>
<td>111</td>
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<td>11</td>
<td>100</td>
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<td>43</td>
<td>4</td>
<td>19</td>
<td>45</td>
<td>432</td>
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<tr>
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<td>229</td>
<td>3</td>
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<td>47</td>
<td>2</td>
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<td>52</td>
<td>488</td>
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Table IV
Waiting Time (in Days) for Transplant Recipients

<table>
<thead>
<tr>
<th>Years</th>
<th>Kidney</th>
<th>Kidney/pancreas</th>
<th>Pancreas</th>
<th>Liver</th>
<th>Heart</th>
<th>Heart/lungs</th>
<th>Lungs</th>
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</thead>
<tbody>
<tr>
<td>1995</td>
<td>502</td>
<td>152</td>
<td>318</td>
<td>82</td>
<td>113</td>
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<td>443</td>
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<td>1996</td>
<td>538</td>
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<td>122</td>
<td>80</td>
<td>84</td>
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<td>474</td>
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<td>412</td>
<td>90</td>
<td>109</td>
<td>739</td>
<td>426</td>
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<td>1998</td>
<td>696</td>
<td>150</td>
<td>331</td>
<td>87</td>
<td>169</td>
<td>166</td>
<td>284</td>
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<tr>
<td>1999</td>
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<td>734</td>
<td>103</td>
<td>80</td>
<td>223</td>
<td>298</td>
<td>301</td>
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<td>640</td>
<td>126</td>
<td>141</td>
<td>104</td>
<td>327</td>
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<tr>
<td>2001</td>
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<td>434</td>
<td>358</td>
<td>114</td>
<td>137</td>
<td>372</td>
<td>258</td>
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<td>2002</td>
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<td>654</td>
<td>506</td>
<td>125</td>
<td>119</td>
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<td>478</td>
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<td>641</td>
<td>231</td>
<td>151</td>
<td>177</td>
<td>894</td>
<td>350</td>
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Table V
Number of Deaths While Waiting

<table>
<thead>
<tr>
<th>Years</th>
<th>Kidney</th>
<th>Kidney/pancreas</th>
<th>Pancreas</th>
<th>Liver</th>
<th>Heart</th>
<th>Heart/lungs</th>
<th>Lungs</th>
</tr>
</thead>
<tbody>
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<td>1995</td>
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<td>ND</td>
<td>ND</td>
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<td>2</td>
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<td>ND</td>
<td>ND</td>
<td>9</td>
<td>12</td>
<td>0</td>
<td>2</td>
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<tr>
<td>2000</td>
<td>23</td>
<td>2</td>
<td>0</td>
<td>13</td>
<td>3</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>2001</td>
<td>25</td>
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<td>1</td>
<td>9</td>
<td>8</td>
<td>0</td>
<td>7</td>
</tr>
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<td>24</td>
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<td>0</td>
<td>18</td>
<td>12</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>2003</td>
<td>12</td>
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<td>0</td>
<td>12</td>
<td>12</td>
<td>2</td>
<td>5</td>
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### Table VI

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

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

### Table VII

**Comparison of Cadaveric Donor Rates Per Million of Population (Worldwide)**

<table>
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<th></th>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Québec</td>
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<td>16.2</td>
<td>17.8</td>
<td>18.3</td>
<td>18.4</td>
<td>17.1</td>
</tr>
<tr>
<td>Canada</td>
<td>15.1</td>
<td>14.4</td>
<td>13.8</td>
<td>15.4</td>
<td>13.5</td>
<td>13.1</td>
</tr>
<tr>
<td>United States</td>
<td>20.4</td>
<td>21.2</td>
<td>21.3</td>
<td>23.5</td>
<td>21.4</td>
<td>21.5</td>
</tr>
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<td>Spain</td>
<td>29</td>
<td>31.5</td>
<td>33.6</td>
<td>33.9</td>
<td>33.7</td>
<td>33.7</td>
</tr>
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<td>France</td>
<td>15</td>
<td>16.9</td>
<td>16.2</td>
<td>16.2</td>
<td>17.8</td>
<td>20.0</td>
</tr>
<tr>
<td>Italy</td>
<td>11.6</td>
<td>12.3</td>
<td>13.7</td>
<td>15.3</td>
<td>17.1</td>
<td>18.1</td>
</tr>
<tr>
<td>Great Britain and Ireland</td>
<td>14.5</td>
<td>13.5</td>
<td>13</td>
<td>13.5</td>
<td>15.5</td>
<td>13.0</td>
</tr>
</tbody>
</table>
The Commission’s consultative activities and acknowledgements

Experts consulted as part of exploratory talks

Ms. Mance Cléroux, Executive Director, Québec-Transplant
Dr. Dana Baran, Medical Coordinator, Québec-Transplant
Mr. Pierre Savard, Director, Institut de génie biomédical, École Polytechnique de Montréal
Mr. Michel Bertrand, Professor/Researcher, Institut de génie biomédical, École Polytechnique de Montréal
Mr. Robert Leblanc, Professor/Researcher, Institut de génie biomédical, École Polytechnique de Montréal

Experts consulted as part of working committee meetings

Discussion theme: Cardiac death or non-heart-beating organ donation

Dr. Réal Cloutier, Collège des médecins
Dr. Hervé Genest, Ministère de la Santé et des Services sociaux
Mr. Michel Lebrun, Ministère de la Santé et des Services sociaux
Dr. Stephan Langevin, Intensivist/Anesthesiologist, Hôpital Enfant-Jésus
Dr. Michael DeVita, University of Pittsburgh Medical Center (by videoconference)
Dr. Robert M. Arnold, University of Pittsburgh Medical Center (by videoconference)

Discussion theme: Consent and families

Mr. Guy Bélanger, kidney donor
Ms. Lisa Goulet, Nurse, McGill University Health Centre, Royal Victoria Hospital
Ms. Carole Lebeau, Coordinator/Clinical Consultant, Québec-Transplant
Mr. Gaétan Leduc, kidney recipient
Ms. Diane Tremblay, mother of a donor
Mr. Denis Mouton, member and former chair of Association québécoise de la fibrose kystique

Discussion theme: Approaches for cultural communities

Mr. Bernard Tremblay, Resource Nurse, McGill University Health Centre, Royal Victoria Hospital
Experts consulted on issues dealing specifically with organ donation and transplantation

Ms. Isabelle Gendron, Executive Director, Fondation Diane-Hébert

Ms. Danièle Drolet, Director, Organ and Tissue Donation Program, Kidney Foundation of Canada

Ms. Mance Cléroux, Executive Director, Québec-Transplant

Ms. Sonia Blais, Chair, Association des greffés de l’Est du Québec

Ms. Jeannine Goyer, Treasurer, Association Générale des Insuffisants Rénaux

Numerous nurses and resource nurses, including

Ms. Lisa Goulet, McGill University Health Centre, Royal Victoria Hospital

Mr. Bernard Tremblay, McGill University Health Centre, Royal Victoria Hospital

Participation in various events

Professional Forum on Organ and Tissue Donation, 2nd edition, Hôtel Delta Québec, Québec City, November 29, 2003

Organ and Tissue Donation Awareness Day, Complexe Desjardins, Montréal, April 19, 2004

Seminar: Allocating Health Resources. Challenges, outlooks, and ethical and bioethical choices, part of 17th Entretiens du Centre Jacques-Cartier, Université du Québec à Montréal, Montréal, October 7 and 8, 2004.

Professional Forum on Organ and Tissue Donation, 3rd edition, Hôtel Gouverneur, Île Charron, Longueuil, November 20, 2004

In October 2004, the following people agreed to comment on the first draft of the working committee’s report:

Dr. Marc Billard, Transplantation Subcommittee, Collège des médecins

Ms. Francine Décary, President and CEO, Héma-Québec

Ms. Hélène Fleury, kidney donor

Ms. Lisa Goulet, Clinical Nurse/Resource Nurse, McGill University Health Centre, Royal Victoria Hospital

Dr. Stéphan Langevin, Intensivist/Anesthesiologist, Hôpital Enfant-Jésus

Mr. Michel Lebrun, Ministère de la Santé et des Services sociaux (Secretary of the committee in charge of preparing an action plan for organ and tissue donation in Québec)

Ms. Thérèse Leroux, Public Law Research Committee, Université de Montréal

Dr. Michèle Marchand, Ethics Committee, Collège des médecins

The Commission wishes to thank all of the people named above as well as all those who took part in the discussion workshops and public consultations in spring 2004. Their input helped spur the Commission’s deliberations and enrich the content of its position statement.
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Assistant Deputy Minister
Ministère des Relations avec les citoyens et de l’Immigration
Québec government

Coordinator
Diane Duquet

* Up to June 2004
** Since October 2004
Organ Donation and Transplantation: Ethical Dilemmas Due to Shortage

The Commission de l’éthique de la science et de la technologie has issued its third position statement on organ donation and transplantation. This statement addresses the ethical challenges raised by the various strategies, either existing or under consideration, to alleviate the transplant organ shortage.

After summarizing the current state of organ donation and transplantation, the Commission examined the ethical challenges raised by living donations, cadaveric donations—both based on brain death criteria & OPO—and the concerns associated with other methods to allocate organ donors and transplant patients. The Commission has set out ten recommendations for political and institutional decision makers.

The mission of CEST consists, on one hand, of informing, raising awareness, gathering opinions, fostering reflection, and organizing debates on the ethical issues raised by developments in science and technology, and, on the other hand, of proposing general guidelines for stakeholders to refer to in their decision making.

Additional resources and other documents on the consultations conducted by the Commission as part of its deliberations can be consulted at www.ethique.gouv.qc.ca.

Comité de l’éthique de la science et de la technologie

www.ethique-gouv.qc.ca