

## POSITION STATEMENT

### ***ETHICS AND ASSISTED PROCREATION: Guidelines for the Donation of Gametes and Embryos, Surrogacy and Preimplantation Genetic Diagnosis***

#### LIST OF ERRATA

#### **SUMMARY**

Page xxi, last paragraph before the box, lines 1 and 2, should read: Also, as mentioned in Articles 42 and 44 of the *Act respecting clinical and research activities relating to assisted procreation*...

Page xxix, last line, should read: reason to believe she is under 21 years of age.

#### **CHAPTER 1**

Page 11, footnote 4, line 2, should read: This definition has been borrowed in part from the definition in article 2 (1) of Bill 26...

Page 21, footnote 52, last two lines, should read: Chapter 1.1 (articles 538 to 542 of the C.c.Q.).

Page 23, footnote 69, line 7: read: 1<sup>st</sup> Session, 39<sup>th</sup> Legislature, 2009.

#### **CHAPTER 2**

Page 31, notes 88 and 89: These footnotes should be read together but in reverse order, starting with note 89.

Page 46, paragraph 2, lines 1 and 2, should read: Also, as mentioned in Articles 42 and 44 of the *Act respecting clinical and research activities relating to assisted procreation*...

Page 47, footnote 165, line 1, should read: In Spain, under article 5.5 paragraph 2 of the Law of 2006

Page 47, footnote 165, last line, should read: article 5.5 paragraph 3.

#### **CHAPTER 3**

Page 71: note 238 should conclude with the following reference: *Assisted Human Reproduction Act*, article 3.

Page 72, paragraph 1, line 1, should read: to believe she is under 21 years of age.

Page 73, footnote 243, column 2: the reference to the Human Fertilisation Embryology Authority Code of Practice should read as follows: HFEA, *Code of Practice, op. cit.*, s. 14.

Page 77, note 266 should conclude with the following sentence: However, under such circumstances, the Directeur de l'état civil could investigate in order to complete the act (article 130 of the C.c.Q.)

Page 77, footnote 268, line 4, should read: the ruling in the case of *O.F. c. J.H.* ...

Page 77, footnote 269: this footnote should read as follows: The International Convention on the Rights of the Child was ratified by Canada December 13<sup>th</sup> 1991, entered into force January 12<sup>th</sup> 1992, and guarantees the right of a child temporarily or permanently deprived of his or her family environment to special protection and assistance provided by the State: (art. 20): <http://2.ohchr.org/french/law/crc.htm>.

Page 77, footnote 271, the second part of this footnote should read as follows: This solution would also comply with article 7 of the International Convention on the Rights of the Child, according to which the child, [...] as far as possible, has the right to know and be cared for by his or her parents.

Page 77, footnote 272, last two lines: should read (paragraph 78 of the ruling).

## CHAPTER 4

Page 95, footnote 329, line 10, the reference to provisions of German law should read as follows: [Sections 1(1) and 1(2)].

Page 113, footnote 384, should read: This remark, it should be noted, also applies to other diagnostic techniques such as PND.

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STATEMENT

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AND ASSISTED  
PROCREATION:  
Guidelines  
for the Donation  
of Gametes  
and Embryos,  
Surrogacy and  
Preimplantation  
Genetic  
Diagnosis



COMMISSION DE L'ÉTHIQUE  
DE LA SCIENCE ET DE LA TECHNOLOGIE



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Diagnosis

The French  
version  
prevails

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the masculine is used without  
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Québec, le 30 septembre 2009

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Monsieur le Ministre,

C'est avec plaisir que je vous transmets par la présente l'*avis Éthique et procréation assistée : des orientations pour le don de gamètes et d'embryons, la gestation pour autrui et le diagnostic préimplantatoire*.

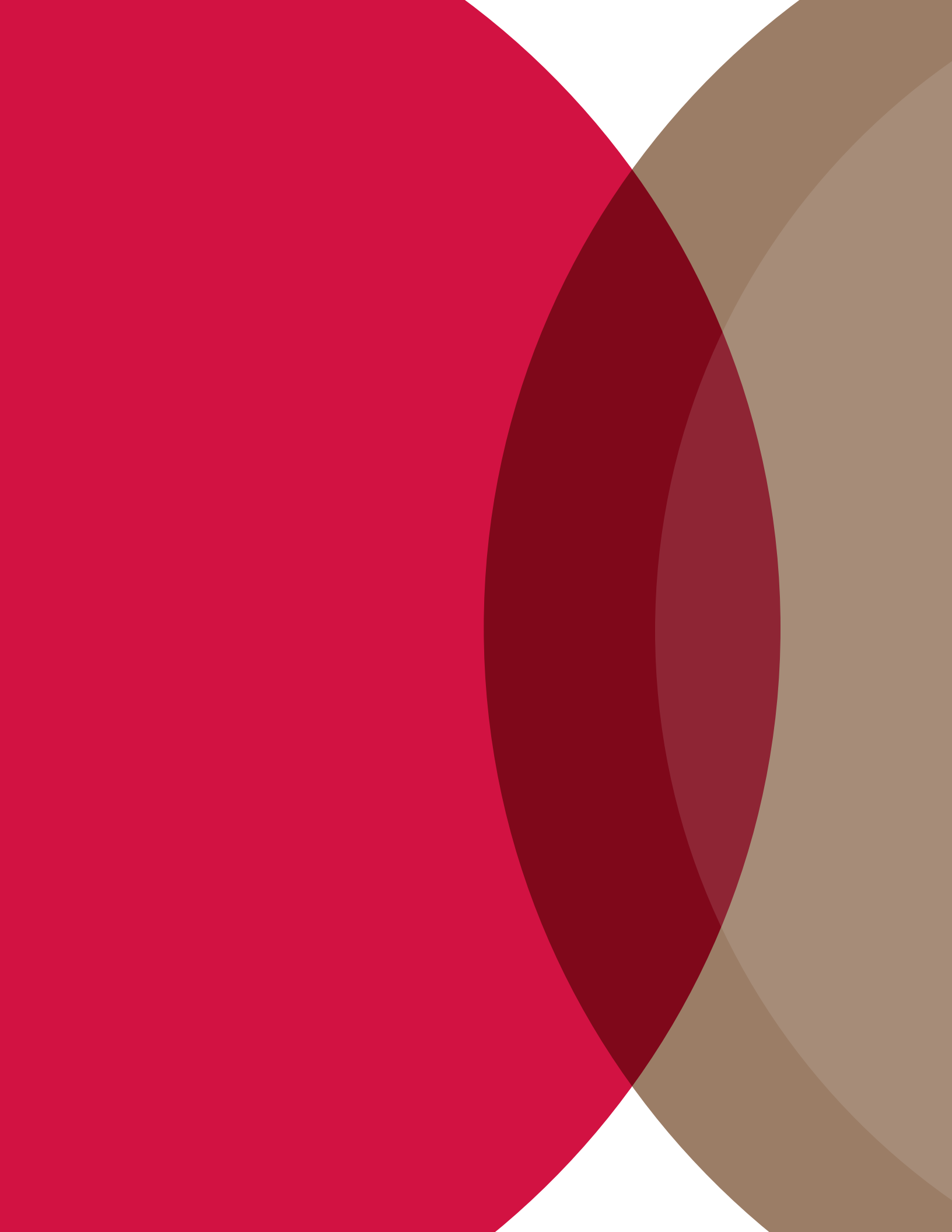
En espérant le tout à votre entière satisfaction, je vous prie d'accepter, Monsieur le Ministre, l'expression de ma haute considération.

La présidente de la Commission

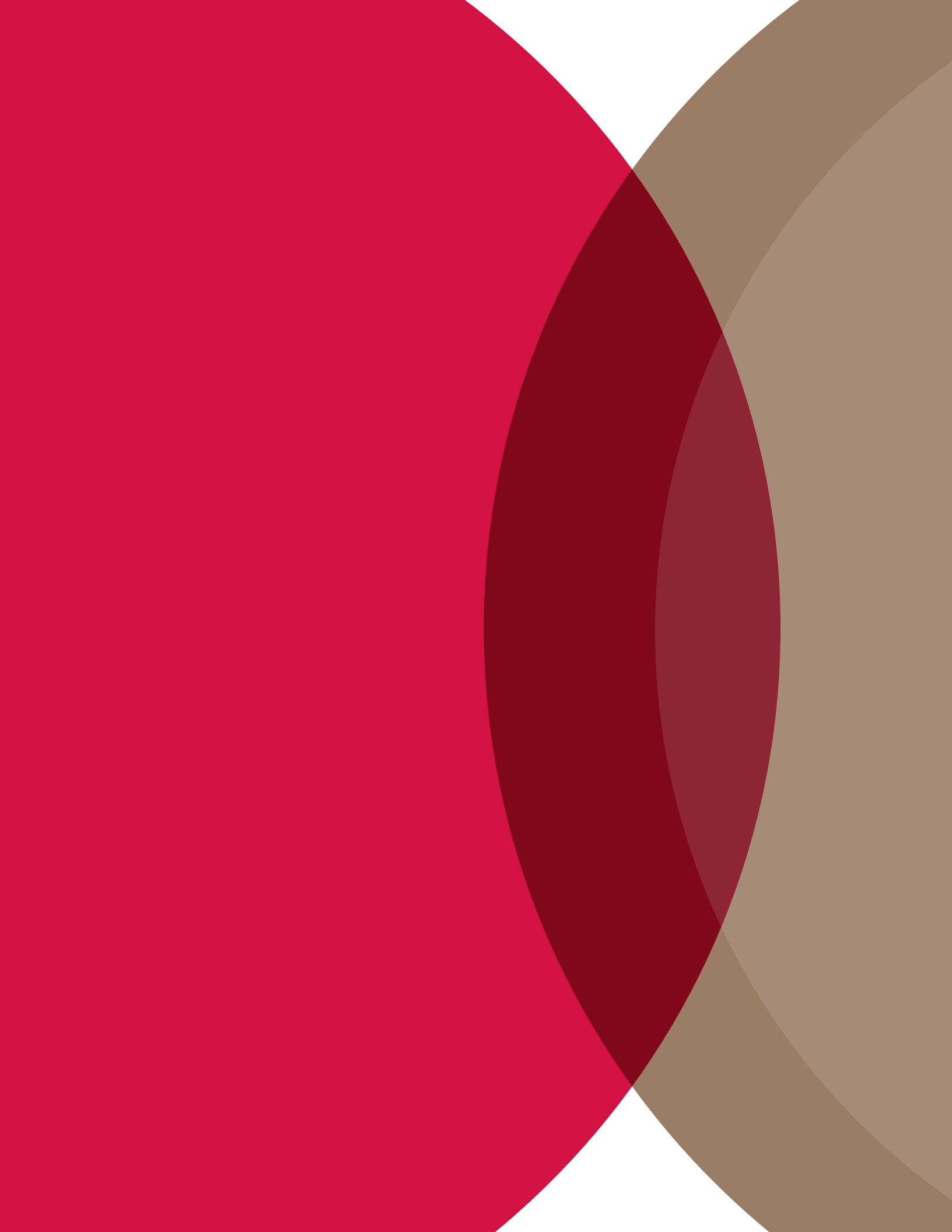


Édith Deleury

c.c. Sylvie Dillard, présidente par interim du Conseil  
de la science et de la technologie



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## LIST OF ACRONYMS

### **AHRC**

Assisted Human Reproduction Agency of Canada

### **AI**

Artificial insemination

### **AID**

Artificial insemination by donor

### **AIH**

Artificial insemination by husband

### **AP**

Assisted procreation

### **ART**

Assisted reproductive technologies/techniques

### **ASRM**

American Society for Reproductive Medicine

### **C.c.Q.**

Code civil du Québec  
(Quebec Civil Code)

### **CCNE**

Comité consultatif national d'éthique  
pour les sciences de la vie et de la santé  
(National Consultative Committee on Ethics  
for Health and Life Sciences) (France)

### **ESHRE**

European Society of Human Reproduction  
and Embryology

### **FISH**

Fluorescent *in situ* hybridization

### **FSH**

Follicle-stimulating hormone

### **GnRH**

Gonadotropin-releasing hormone

### **hCG**

Human chorionic gonadotropin

### **HFEA**

Human Fertilisation and Embryology Authority  
(United Kingdom)

**HLA**

Human leukocyte antigens

**ICSI**

Intracytoplasmic sperm injection

**INSPQ**

Institut national de santé publique  
(Quebec National Public Health Institute)

**IUI**

Intrauterine insemination

**IVF**

*In vitro* fertilization

**IVM**

*In vitro* maturation

**LH**

Luteinizing hormone

**OHSS**

Ovarian hyperstimulation syndrome

**OS**

Ovarian stimulation

**PCR**

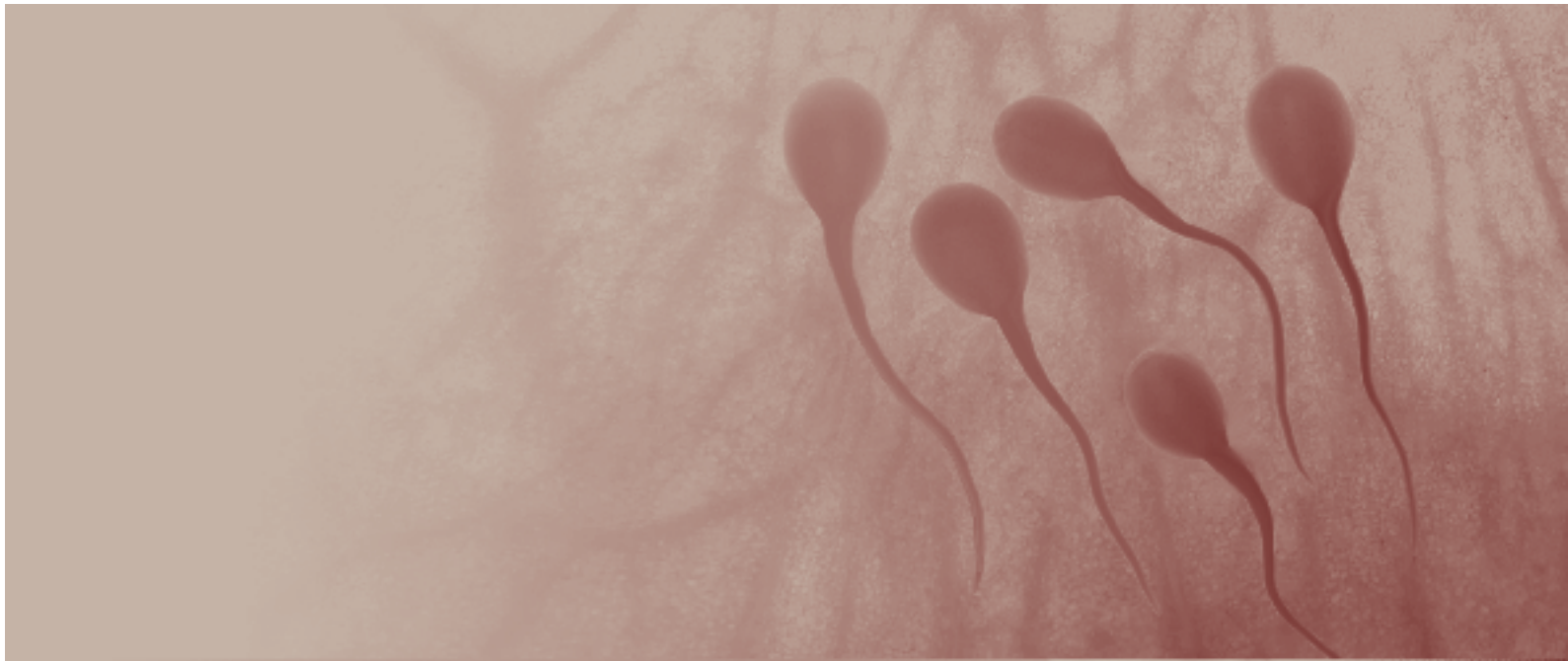
Polymerase chain reaction

**PGD**

Preimplantation genetic diagnosis

**PND**

Prenatal diagnosis





SUMMARY AND RECOMMENDATIONS



## SUMMARY AND RECOMMENDATIONS

The themes related to the beginning and end of life leave no-one indifferent. Assisted procreation (AP) is no exception to this trend. AP raises passions and provokes debates, probably because it evokes deep feelings and touches a sphere of human life rich in emotional and symbolic values. However, a clear-sighted analysis of ethical issues requires a more detached and more rational view of practices that are current, or could become current in the near future. One of the challenges the Commission has faced in this position statement lies precisely in striking a balance between the heart and reason.

In this position statement, the Commission is conducting a “thorough analysis of the ethical and societal values connected” to AP, in order to address the issues submitted to it by the Minister of Health and Social Services. Given the mandate entrusted to it, the Commission’s thinking has a single aim: namely, to enlarge on work already underway

at the Ministry of Health and Social Services and to present ethical considerations related to three practices: gamete and embryo donation, surrogacy and preimplantation genetic diagnosis (PGD).

From the outset, two preliminary remarks should be made; the Commission has kept them in mind throughout the process leading to production of this position statement. First, the Commission considers that, in addition to AP, the adoption of children is an alternative worth considering, in cases where a person is having difficulties conceiving naturally. In addition, the Commission considers that there is no such thing as a “right to a child,” and as a result the State is not required to satisfy the requests of all citizens where assisted procreation is concerned.

## THE CONTEXT OF ASSISTED PROCREATION

The term “assisted procreation” refers to various forms of support for human reproduction using medical or pharmaceutical technologies, or laboratory manipulations that attempt to overcome problems of infertility in heterosexual couples, or the inability to procreate naturally in the case of homosexual couples or single women. These technologies also allow fertile couples for whom there is a risk of transmitting a serious disease, whether genetic or viral, to try to have children who will not suffer from such a disease.

Assisted procreation includes the following activities: ovarian stimulation, the collection, processing, *in vitro* manipulation and preservation of human gametes, artificial insemination with sperm provided by a spouse or donor, preimplantation genetic diagnosis, and the conservation and transfer of human embryos.

Although these practices are increasingly seen as routine, safe and effective procedures, they are not risk-free. At a more fundamental level, however, assisted procreation has disrupted our symbolic points of reference, our representations of the family and blood relationships, of the child, and of the existence and intrinsic value of the human being.

### **From adultery to the desire for a child or to the right to a child**

In the eighteenth century, experimental biology first explored assisted procreation as a way of overcoming male infertility. Since that time, AP has continued to develop discretely in medical practice. From the outset, using technological means to assist reproduction has raised moral issues, particularly with regard to sexual morality.

The involvement of a third person in the conception of a child could be seen as a form of adultery, and physicians have therefore developed technical measures so that medical practice cannot be equated with morally unacceptable sexual behaviour. The notion of medical indications seems to have made the transition possible between, on the one hand, applications considered socially and morally acceptable and, on the other, applications likely to destabilize social life and an individual's emotional and mental equilibrium.

The notion of medical indications has provided a point of departure for legislators, in setting legal frameworks for the drafting of laws and practice guidelines. This notion is no longer the primary justification for access to assisted reproductive techniques (ART) – actually, access to such techniques is no longer solely related to a diagnosis of infertility, and is now more broadly related to the desire to have a child. Gradually, this desire to have a child has increasingly been transformed into a “right to a child,” which in turn includes the right to use all available means to have a child.

Nowadays, assisted procreation has a recognized and institutionalized place, which has allowed many people to fulfill their desire to have a child. Moreover, it has become a major and highly profitable activity in several countries, and has become widespread in large part due to the development of new technologies, the emergence of new societal values and social change.

### **Today's techniques are more effective but also involve risks**

Clinical assisted procreation activities involve many different kinds of procedures; they depend on the cause of infertility or sterility, which prevents conception of a child, or on the desire to have a child among people who have no fertility problem, but who cannot procreate naturally.

These techniques involve several risks. The most important risk is multiple pregnancy, which constitutes a risk for the health of mothers, fetuses and the unborn, regardless of the reproductive technique used. Other risks include those associated with ovarian stimulation, with stress and the frustration that accompany such a complex technology, psychological risks resulting from an inability to procreate, as well as risks for children (these latter have been poorly documented to date).

## **Beyond medical indications: the evolution of the concept of the family and its transposition in the legal system**

To better understand the general trends affecting the means by which a society reproduces itself, we must first inquire into the characteristics which a family needs in order to be regarded as such within a community or group. Currently, the traditional nuclear family (man, woman and children) is no longer the only socially accepted model, although it remains nevertheless the dominant model.

However, since 2002 assisted procreation has become a real prospect for single women or homosexual couples who want a child without resorting to adoption, while being biologically related to the child and although they do not themselves have a fertility problem. It is now possible to consider assisted procreation as a means for establishing a filial bond that is both full and autonomous.

In terms of the legal framework for AP, the federal Parliament of Canada passed the *Act respecting assisted human reproduction and related research* in March 2004. This law prohibits a number of practices and establishes the legal framework for activities considered legal. In December 2004, the Quebec government referred the constitutionality of this federal law to the Court of Appeal of Quebec on the grounds that it went beyond the legislative competence of the Parliament of Canada and encroached on the power of the provinces to legislate in matters of health. The Court of Appeal struck down the provisions contained in the reference. The federal government has appealed to the Supreme Court of Canada, however, to determine which level of government actually has power to legislate in this area.

Moreover, in April 2009 the Quebec Minister of Health and Social Services introduced a bill to regulate clinical activities and research in the area of assisted procreation. This bill was adopted by the National Assembly. The *Act respecting clinical and research activities relating to assisted procreation* received assent on June 19, 2009.

The elements outlined above highlight the fact that the development of assisted reproductive techniques available in Quebec is not the only factor that can explain the recent surge in the use of AP; a series of factors emerging over the last few years has also contributed to the situation. The development of medical practice raises questions about such important aspects as the social representation of filiation; the desire to protect those persons relying on assisted procreation and the children born as a result requires thorough ethical reflection in order to guide the actions of stakeholders. The first issue addressed by the Commission in this regard concerns gamete and embryo donation.

## **GAMETE AND EMBRYO DONATION: BALANCING THE INTERESTS OF STAKEHOLDERS**

The Commission has focused on clinical practice and its implications for third-party contribution to parental project, in order to better understand the issues and values underlying this participation.

### **Clinical practice**

When resorting to a third-party contribution to the parental project, infertile people must meet a number of requirements which have several similarities. Gamete donors and women receiving donated sperm or eggs must first undergo basic medical examinations in order to assess the health of the persons involved. In addition to medical assessments, psychosocial assessments are also made, and women recipients must complete a consent form that provides important information about the proposed technique.

### **Sperm donation**

The change in practices surrounding insemination with donor sperm is largely related to the development of semen conservation techniques. Actually, at room temperature fresh semen can only be conserved for one hour. However, sperm can now be frozen indefinitely in liquid nitrogen using a technique called cryopreservation. This technique has led to the establishment of sperm banks.

Artificial insemination (AI) refers to all forms of insemination undertaken without sexual intercourse. There are three main categories of AI, depending on whether sperm is fresh, is supplied by the spouse or by a donor.

### **Recipient profiles**

Clinics enable people whose infertility is medically proven to gain access to donated sperm. Heterosexual couples, single women and lesbian couples have access to such donations.

In 2007, according to data obtained by the Commission from one of the clinics consulted, about 50% of donated sperm was used to alleviate a medical indication or unexplained infertility. The remainder of donated sperm went to women who had applied for it on social or personal grounds (about 40% were homosexual women and 10% were single women).

### **Donor profiles**

Potential donors must be between 18 and 40 years of age, have a stable sexual life (with only one sexual partner during the previous six months), be in good physical and mental health, and know the identity of their biological parents so their medical history can be determined.

### **Outcomes**

In Quebec, a single clinic was consulted which runs a sperm bank and distributes sperm through fertility clinics in the province. This clinic estimated that over the last ten years, 1,600 children were born as a result of donated sperm. The vast majority of these donations were used in artificial insemination programs (98%) rather than in *in vitro* fertilization (IVF) programs (only 2%). The clinics consulted indicate that assisted reproductive techniques using sperm donation obtain substantially the same outcomes as conjugal insemination programs.

## Egg donation

Egg donation is usually resorted to in the case of women who lack ovaries, suffer from ovarian failure, have experienced early menopause or are too old to procreate naturally. Fertilization of a spouse's sperm and a donated egg must take place *in vitro*. Egg donation requires a greater time commitment from the donor than sperm donation. Actually, the egg donor adheres to part of the IVF protocol, namely by taking medication to regulate and stimulate the production of ova before their removal.

### Recipient profiles

In general, women who use donated eggs do so because of their age (egg production decreases with age), because they experience early menopause or because they have suffered several *in vitro* fertilization setbacks with the use of their own eggs.

### Donor profiles

The vast majority of egg donors are recruited by applicants. Egg donors must be between 18 and 35 years of age, exhibit no exclusion criteria as defined by fertility clinics, be healthy and have a primarily altruistic motivation. A psychologist or nurse meeting a potential egg donor seeks to understand the woman's underlying motivations, her understanding of risk and her feelings about the fact that she will never be the social mother of the unborn child.

## Embryo donation

In Canada, embryo donation is a very rare practice. Only one clinic seems to have an embryo donation program. In Quebec, embryo donation does not yet exist, but at least one clinic plans to create such a program.

People are generally reluctant to donate their embryos once they are engaged in the full process of procreation. They prefer to keep a bank of frozen embryos, destroying them or offering them for research purposes once the project of having a child has been completed. Also, many couples find it difficult to decide the fate of spare embryos.

### The values at stake

For the Commission, gamete and embryo donation challenges the key values of the welfare of the child, the dignity of the human person, equality, reproductive autonomy and privacy.

The well-being of children is the responsibility of all stakeholders and implies that the child resulting from AP faces the same opportunities in terms of physical and psychological development as naturally conceived children.

The value of human dignity is contained in the principle that the human person itself should be considered as an end and not as a means to an end. This value excludes all forms of instrumentalization, reification and commercialization of the human body, its tissues, organs and products.

In terms of equality, the Commission has noted the disparities caused by Quebec legislation between gay and lesbian couples, men and women and between women. On the one hand, female lesbian couples can resort to artificial insemination with donated sperm, whereas co-parenting, which would allow a gay couple to have a child with a pair of homosexual women, is prohibited under Quebec law. On the other hand, a single woman can undertake a parental project through recourse to donated sperm, whereas the male equivalent is not possible because a single man would need recourse to a surrogate mother, something which is prohibited under Quebec law. Furthermore, by allowing a homosexual woman to become a mother without giving birth, the law creates a disparity between lesbian women and heterosexual women. In fact, when heterosexual women cannot bear children, they cannot aspire to become mothers, since a mother is the female person giving birth to the child. In addition to these disparities, the Civil Code draws a distinction between adopted children and children resulting from the donation of gametes: adopted children are able to access information about their biological parents starting at the age of 14 years, whereas children resulting from the donation of gametes are not allowed to access such information.

Reproductive autonomy may be defined as the ability of a person or couple to decide independently whether to reproduce or not and to choose the means to do so. Paradoxically, reproductive autonomy may imply that a couple or person will need a third person or a medical technology to achieve its parental project. While Quebec society recognizes the values of freedom of choice and autonomy, these values must also be reconciled with other values such as human dignity, welfare and the health of women and children.

Respect for privacy can be defined as the right to control information concerning us and to protect this information. As a result, this concept implies the freedom for individuals to keep certain information about them confidential. However, a component of the right to privacy – respect for one's identity – includes the right of the child to have access to its origins.

### **Ethical issues**

The third-party contribution to the parental project, through gamete or embryo donation, raises issues of two kinds. The first concerns the development of the child resulting from such a donation. This issue concerns the influence of the genetic bond in relation to the social bond, as well as the child's access to its origins, in conjunction with respect for the privacy of its parents and the right of donors to remain anonymous. The second issue concerns the concept of the dignity of the human person, the commercialization of the human body and its products, and the instrumentalization of human beings.

### **The development of children resulting from a donation**

Few studies on the fate of children resulting from a donation are able to shed light on their relationship with their parents and with donors possibly involved in the parental project. Indeed, the first studies on children resulting from AP were conducted primarily from an epidemiological perspective. While somatic data are beginning to emerge, very few analyses focus on psychological relationships and on parent-children interactions.

*Filiation: what importance should be accorded to genetics?*

The social bond between parents and children is a major component of the set of problems related to AP. Practices such as adoption or the restructuring of families after separation and divorce have changed the structure of the traditional nuclear family and have made social filiation more important.

However, couples or single people who wish to have a child “of their own”, are ready to resort to increasingly sophisticated methods or involve a third person in their parental project without this latter contribution being acknowledged. The desire to have a child biologically related to them may motivate some people to seek every means to achieve their end.

Why do people seek genetic filiation? Why is this filiation becoming increasingly important as reproductive technologies are developed? According to one hypothesis, the development of technology leads people to attribute greater value to the genetic bond in relation to the social bond. In this view, the use of available AP techniques thereby ensures that those unable to fulfill their desire for children are now able to exhaust every opportunity to have a child “of their own.”

Also, as mentioned in Articles 41 and 42 of the *Act respecting clinical and research activities relating to assisted procreation*, the Commission believes that scientific studies should be undertaken on the physical and psychological development of children resulting from AP and on the physical and psychological health of women participating in IVF protocols.

*The Commission therefore recommends:*

#### **Recommendation No. 1**

- That the Minister of Health and Social Services give the Institut national de santé publique (INSPQ) the mandate to establish a centralized mechanism for collecting non-nominal data in order to monitor the development of children resulting from assisted procreation, as well as the health of persons involved in assisted procreation;
- That this database be accessible to public health officials in fulfilment of the monitoring program, and to researchers whose research projects have been duly approved by the competent authorities, including a research ethics committee.

*Access to origins: should anonymity be lifted or not?*

In Quebec, gamete donation is normally anonymous. Gamete donors have neither rights nor obligations towards children whose conception results from donated gametes. On the other hand, certain mechanisms make it possible to reconcile the anonymity of a donor with the child's need to obtain information about the donor. This applies particularly in the case of medical information, knowledge of which may be necessary to protect life and health of the child.

However, anonymity gives priority to respect for the privacy of donors and to secrecy surrounding the circumstances of the child's birth. In so doing, by extension, it also deprives the child of the option of gaining access to its origins. According to many observers, the risk of disclosure in inappropriate circumstances of secrets surrounding the birth of children resulting from donations, and the legal impossibility for these children to gain access to information concerning them, come into conflict with the construction of identity, the well-being of children and the sense of belonging to a family.

The Commission recognizes that in some cases, because of the family and cultural context in which the child is developing, disclosure is not always in its interest. It considers nonetheless that fertility clinics should routinely offer their customers a form of counselling to help them make an informed decision about the appropriateness of informing the child about the circumstances surrounding its birth. In this regard, counsellors should clearly highlight the potential effects of secrecy on the child and on the whole family.

The Commission believes in the importance, on the one hand, of ensuring that a balance is achieved between the interests involved and, on the other, of giving precedence to the well-being of the child, while avoiding the creation of disparities between adopted children and those resulting from AP. It believes that it would be wise to proceed one stage at a time.

*Whereas it is better to let gamete donors be the first to lift the anonymity of their donation, instead of proposing a total lifting of anonymity, the Commission recommends:*

**Recommendation No. 2**

- That the Quebec government amend the Civil Code of Quebec to address the disparity in rights between adopted children and children resulting from donations, with respect to access to their origins, by applying the same practice as in matters of adoption;
- That appropriate counselling be offered routinely, not in a context of self-regulation, but as part of a regulatory framework instead. Such counselling should address both gamete donors and people resorting to donated gametes or embryos, in order to make them aware of the importance for the child of knowing its origins and the implications of lifting anonymity.

**Respect for the dignity of each human being**

Human dignity is a vague and hard-to-define concept, but is nonetheless a concept at the heart of values professed by democratic societies, including Quebec society. In this regard, and from an ethical perspective, the donation of gametes raises the issue of the instrumentalization of the person.

### *The non-commercialization of the human body and its products*

The Commission rejects outright any idea of challenging the principle enshrined in law of the non-commercialization of human body. However, altruism does not seem to be enough of a motivation to attract a sufficient number of gamete donors to meet the needs of infertile people. Different measures involving some form of monetary exchange have been developed in the context of gamete donation. In order to pursue further analysis in this position statement, the Commission identifies three monetary measures, namely compensation, the payment of an indemnity and the reimbursement of expenses.

The Commission has found that this apparently straight-forward question does not easily yield an answer. Indeed, it may at first seem obvious that the non-commercialization of the human body and its products should take precedence over all other considerations. However, the value of equity affects various facets of the set of problems involved in assisted procreation, and to varying degrees – and this in turn is transforming reflection itself into a true dilemma. The Commission also shares the concern of couples or individuals who wish to obtain a gamete donation and who are somehow penalized by the lack of gametes available to meet their needs. Accordingly, while compensation is already prohibited, should an indemnity package also be prohibited, at the risk of creating inequality between egg donors and sperm donors? Should such an indemnity be allowed instead, at the risk of creating an inequality between better-off donors and those less-well-off? Is it acceptable to prohibit a practice likely to increase the number of gamete donors, which could possibly compensate for the scarcity of gametes?

Nevertheless, the Commission believes that not everything should be reimbursed or indemnified, and that donation is a personal choice requiring a good dose of altruism. Given that human products are involved, the scarcity of these products should not be invoked as a reason for the use of monetary incentives. A risk-benefit analysis shows that the scarcity of gametes alone (and the benefits of a greater availability of gametes where donations are subject to higher compensation or indemnity) do not constitute a sufficient reason, considering the risks that could arise from compensation or overcompensation of gamete donation (the risks of exploitation, discrimination, commercialization of the human body, health risks for women, etc.). The reimbursement of expenses upon presentation of receipts would attract people who are really interested in the idea of helping infertile people. Moreover, such a practice would prevent donors from disbursing funds in order to make their donation, while acknowledging the action they have taken.

It could be possible to envisage setting up a bank managed by a central agency, like Héma-Quebec, for example, mandated to take over the management of donated gametes produced in Quebec and, in the event of a shortfall, to obtain sperm from outside of Quebec.

*Whereas donation is based on altruism and the non-commercialization of human body is an inviolable principle, the Commission recommends:*

### **Recommendation No. 3**

That the Minister of Health and Social Services establish an agency to regulate approved clinical practices for the storage of gametes and embryos, for recruitment, reimbursement of expenses and the traceability of gamete donors, and for raising awareness of these risks and responsibilities associated with their actions.

#### **The non-instrumentalization of individuals**

Is there a societal obligation to satisfy the desire of infertile people for a child, at all costs? This is the main issue the Commission has raised with respect to the selection of gamete donors by clinics and parents. The Commission also wonders how such a selection could lead to the instrumentalization of persons.

In ethical terms, the attempt to determine a maximum number of characteristics for the unborn child could hamper this child's symbolic freedom, namely to be born for itself as a unique individual with its own project. Indeed, from that time on, the question at issue is no longer that of having a healthy child, but of having a child with specific characteristics that meet the expectations of prospective parents. In the United States, prospective parents may consult "catalogues" of sperm donors, choosing a donor based on a pedigree that suits them (education, physical, artistic or athletic skills, etc.). This practice suggests that the child is a consumer product, an object to be customized according to the wishes of parents.

For the Commission, such a practice is unacceptable and constitutes the instrumentalization of the unborn child.

*Whereas Quebec society should avoid developing practices such as creating "custom-made baby" through the selection of gamete donors, and whereas, under current conditions, the confidentiality of origins is protected and the minimum matching of physical characteristics with the father poses no risk to the child and may even encourage its integration into the family and society, the Commission recommends:*

### **Recommendation No. 4**

That the only permissible criteria for donor selection, in addition to medical criteria, be physical criteria for matching with one intentional parent, where this seems to be justified by the welfare of the child.

#### **The supply of gametes for infertile individuals**

Although the Commission gives priority to the interest of the child and the dignity of the human body and its products, it has decided to consider five options for mitigating the effect of any (partial or complete) lifting of anonymity and the impact of freely donated gametes on the offer made to infertile persons: directed donation, paired donation, shared donation, posthumous donation and embryo donation.

### *Directed gamete donation*

In the case of directed donation, the couple or single woman recruits a donor (a sister, friend, colleague, etc.) who provide her own eggs. This type of donation is not anonymous. This gives rise in turn to a number of ethical concerns: do the donors risk being pressured by those around them to donate? What assurance is there that no exchange of money between people is involved? In addition, recipient couples or women may fear that the donor could interfere during pregnancy or become too attached to the child, or that she could one day tell the child all about its status. Conversely, there are cases where donation has strengthened the bond between the donor and the recipient or recipients. The Commission considers that the directed donation of gametes is acceptable as long as donors and recipients receive appropriate counselling so that they may make an informed decision.

Using donations from within the family raises many ethical issues, including the impact of this practice on the sociological and anthropological foundations of parenthood, and even on the identity of individuals. Two scenarios are possible: intragenerational and intergenerational donation.

An intragenerational donation refers to gamete donation between collateral relatives, that is, between two siblings or within the extended family. The Commission believes that intragenerational donations require appropriate counselling to ensure that no family pressure is exerted on potential donors and that each party to the donation understands the emotional risks associated with such donations, including risks arising from the rearrangement of the filial bonds.

Intergenerational donation, for its part, is far from being universally accepted. Since it involves the donation of gametes or embryos from one generation of a family to another generation, the incestuous character of the donation constitutes a significant source of discomfort. Moreover, most authors dealing with the donation of gametes from a sociological or anthropological point of view use the argument of incest in opposing this type of donation.

Family pressure is also a major component of this problematic situation. There may be pressure on the mother to donate her eggs to her daughter (out of guilt or from a sense of duty) and once the opportunity to do so arises, it may seem impossible to backtrack.

Moreover, intergenerational directed donations could have serious emotional consequences for children because of the resulting confusion in family relationships. In addition, given that the mother may somehow be the grandmother, aunt or sister of the child conceived in this way, temporal and generational boundaries are being transgressed. Theoretically, by means of directed embryo donation, a woman could bear her own brother (for example a couple having kept frozen embryos following fertility treatments could provide its own daughter with surplus embryos). The opposite could also happen, for example in the case where older women used the eggs of their daughter.

*Whereas the directed intragenerational donation of gametes may be acceptable if properly monitored, whereas intergenerational directed donation endangers the welfare of unborn children, the Commission recommends:*

#### **Recommendation No. 5**

- That the intragenerational donation of gametes be practiced in an environment that eliminates any possibility of consanguinity;
- That those involved in intragenerational gamete donation receive appropriate counselling so that they may properly assess the potential impact on filial bonds and their relationship with the donor as well as the future relationship between the donor and the child;
- That intergenerational donation be prohibited since it transgresses temporal and generational boundaries.

#### *Paired donation*

Paired donation resembles directed donation except that the donor does not provide her eggs to the specific couple or person recruiting her. Instead, she will be matched with another couple or single person who has recruited a donor. The Commission considers that paired donation is acceptable, provided that parties receive appropriate counselling.

#### *Shared Donation*

The shared donation program aims to convince women and couples who cannot afford to pay for their treatment to donate some of their eggs in exchange for a reduction in the cost of treatment. The question then arises: can cost-sharing be construed as a form of pressure, not to mention commercialization?

Shared donation is not contrary to the interests of the child, but is of little interest given that first cycles of IVF are reimbursed by the State in Quebec. However, the main interest of this type of donation is the financial incentive, which runs counter to the principle of non-commercialization of the body, unless egg sharing has an altruistic motivation. In the latter case, it is acceptable, provided that parties receive appropriate counselling.

#### *Donation and posthumous insemination*

The Commission has studied the following scenarios: gametes from a donor who is now deceased, gametes collected from a man or woman after death, gametes already collected in fulfilment of a parental project before the death of the spouse, embryos created in fulfilment of a parental project before the death of the spouse. The Commission has devoted particular attention to two of these cases because of the ethical issues they raise.

**Gametes collected from a man or woman after death.** The Commission believes that in this context, precedence should be given to compliance with the previously expressed wishes of the donor. In this regard, it recalls and endorses the principle stated in Article 8(2) of the *Canadian Assisted Human Reproduction Act*, namely that it “No person shall remove human reproductive material from a donor’s body after the donor’s death for the purpose of creating an embryo unless the donor of the material has given written consent, in accordance with the regulations, to its removal for that purpose.”

*Whereas it is possible that this provision may be declared unconstitutional by the Supreme Court on the grounds that it encroaches on the powers of the provinces, the Commission recommends:*

### **Recommendation No. 6**

That the removal of gametes from a deceased person be prohibited if the deceased person has not previously consented to it.

**Embryos created in fulfilment of a parental project before the death of the spouse.** The Commission believes that the surviving spouse go through a minimum period of reflection before the embryo is transferred. In addition, due attention should be paid to pressures possibly exerted by in-laws.

There are very few studies on the subject. However, there is little difference between the situation of children developing in a single-parent context and children resulting from the insemination of single women.

*Whereas the widow needs to go through a period of reflection, while respect needs to be upheld for the reproductive autonomy of individuals as part of a parental project, the Commission recommends:*

### **Recommendation No. 7**

That insemination or embryo transfer be permitted only on condition that all the following criteria are met:

- The removal of gametes or fertilization has occurred before death;
- There is written consent of the deceased indicating his or her agreement as provided in their parental project;
- The widow was able to go through a period of reflection and receive adequate counselling in order to make an informed decision.

### *Embryo donation*

Embryos for donation are spare embryos that are no longer need to implement a parental project. Embryo donation is a rare practice in Canada, and does not yet exist in Quebec. Many couples find it emotionally difficult to decide the fate of surplus embryos. Furthermore, a significant proportion of frozen embryos are stored in the banks of fertility clinics, where they await destruction or use for reproductive purposes or for research.

It is important that donors and recipients receive professional and independent counselling about the disposal of spare embryos. This counselling should be available to potential donors in the early steps of assisted procreation so they can prepare for the possibility, on the one hand, of donating their embryos and, on the other hand, of being in a position to provide informed consent without undue influence from anyone.

*Whereas the stakeholders involved need to be adequately informed, the techniques for freezing embryos are improving, and embryo donation means that recipients avoid the risks and disadvantages associated with IVF, the Commission recommends:*

#### **Recommendation No. 8**

- That people who use assisted procreation receive all information necessary to make an informed decision about embryo donation at an early stage of the process, but also later, when the assisted procreation process has been completed or abandoned and when there remain spare embryos;
- That programs based on anonymous donations of surplus embryos be favoured. To this effect, that people be encouraged after the initial success of assisted procreation to provide their written consent to donate their surplus embryos. After a period of three years, unless the owners of these embryos have made a specific request use these embryos, extend their conservation or destroy them, the embryos should be donated anonymously.

#### **Prevention and education: acting before the initial stages of assisted procreation**

Among people resorting to assisted reproductive technologies, many do so because of infertility or subfertility. Whereas these techniques are rarely the first choice for couples, it is crucial to focus more research on the causes of infertility, including the postponement of pregnancy. By taking steps pro-actively, through prevention and education, the Commission considers that demand for AP will likely decrease, thereby reducing the number of people exposed to risks associated with these techniques. More preventive measures should be taken to address male and female infertility.

*Whereas prevention may take the form of public policies aiming to raising awareness among the population of the causes of infertility and the risks of childbearing at a later age, the Commission recommends:*

#### **Recommendation No. 9**

- That the Minister of Health and Social Services fund a public awareness campaign on the known causes of infertility and the ways to preserve fertility;
- That the Quebec government reinforce socio-economic measures and public policies that incite people to engage in parental projects at an earlier age;
- That the Quebec government fund research programs on the prevention of infertility.

## SURROGACY: MAINTAINING THE LEGAL *STATUS QUO*

Surrogacy generally includes all situations where a woman goes ahead with a pregnancy, not because she intends to keep the child and take on the social role of mother, but in order to hand the child over, at birth, to a person or a couple with whom she has contracted for this purpose.

New kinds of surrogacy are emerging nowadays. The most common kind is where the surrogate mother is inseminated with sperm from the spouse of a woman who can neither conceive nor carry a child. In this case, the egg used is provided by the surrogate mother. In fulfilling the roles both of direct parent and of surrogate mother, this woman may thus be considered a “substitute mother”. A homosexual couple may also consider recourse to a surrogate mother. The semen of one of the homosexual partners is then used for intra-uterine insemination of the surrogate mother.

With the development of assisted procreation, a new form of surrogacy has emerged: one in which the eggs of the surrogate mother are not used for fertilization and where the surrogate mother carries and gives birth to the child. In this situation, an embryo already conceived *in vitro* is transferred into the uterus of a woman who will carry and give birth to it, on behalf of the couple or person whose gametes were used or, in some cases, who have resorted to donors.

It is important to understand that in such cases, the woman has no genetic bond with the child she carries for a third person. This is also why IVF tends to be used rather than insemination of a surrogate mother with the spouse’s sperm, in order to prevent the surrogate mother from becoming too attached to the child.

In Quebec, there is very little documentation about surrogacy since the contracts providing for it are not binding and have no legal value: in the eyes of the law, these contracts are absolutely null and therefore unenforceable.

### The legal framework

In Quebec, surrogacy contracts are not recognized in law. They are considered unlawful, because they are contrary to public order.

However, while surrogacy contracts are considered unlawful and therefore unenforceable in civil law, they may not strictly speaking be illegal, in other words, punishable by fines or imprisonment. Indeed, the Canadian *Assisted Human Reproduction Act* criminalizes certain practices but does not prohibit surrogacy as such; the act only prohibits payment for surrogate motherhood, payment of intermediaries, or the placing of advertisements to obtain the paid services of a surrogate mother. On the other hand, the law prohibits members of the medical profession from assisting a female person to become a surrogate mother, knowing or having reason to believe she is under 18 years of age. Although the act

presents the practice *a contrario*, the practice is nonetheless subject to control and, in some way, is legitimized by federal law. Consequently, *a priori*, a dichotomy exists between criminal and civil law, which has had the effect of causing some confusion between what is void and what is illegal, for clinicians practicing in this area.

### The context of practice

For the time being, the practice of surrogacy is somewhat limited in Quebec. It is however possible that Quebec couples may have resorted to surrogates abroad, just as Quebec women may have been recruited by people living abroad to carry their child. Given the lack of data in this regard, it is not possible to assess how high the demand for surrogates is, or to determine what agreements are being concluded and what the real motivations of surrogate mothers are. Yet, as difficult as it is to measure the scope of surrogacy, the practice exists in Quebec as elsewhere, and it raises a number of ethical issues.

### Ethical issues

The issues at stake are much the same as those the Commission has identified for gamete donation, with one exception. It may be difficult for the child to establish who its parents are, and this may become a source of conflict, even to the point where the child has no status, in other words the child is without either mother or father. For the child, surrogacy constitutes a major issue, quite apart from the difficulties the child may face in having two mother figures. In the Commission's view, the well-being of the child is the primary value to be considered and goes to the heart of the issues raised by surrogacy. However, the practice of surrogacy also affects other values, including women's health and autonomy, and the dignity of the human person, which involves the principle of the non-commercialization of human body, a principle opposed to any form of instrumentalization of the person.

### The status of the child

In Quebec law, motherhood is determined by the birth of a child, which is duly recorded in an attestation of birth; motherhood cannot be challenged on the grounds that the egg or embryo is not from the woman who carried the pregnancy to term. It is from this attestation of birth and the subsequent declaration of birth, signed by the parents, that the birth certificate is established, providing normal proof of filiation.

Based on these premises, three scenarios are possible: the surrogate mother decides to keep the child; she hands it over to the prospective parents – and in so doing, she fulfils her obligation to them; or, finally, none of the actors involved wants to keep the child and it is left without status. In each case, the child's filiation is problematic, and it may be necessary to settle the matter in court.

### The development of the child

Contrary to egg donation, surrogacy can create another type of cleavage in motherhood: the social mother may be the genetic mother, although she is not the one carrying the child.

Surrogacy therefore highlights a dichotomy, a distinction between the surrogate mother and the fetus itself. Surrogacy underlines the idea that the fetus is a being “apart” from the woman carrying it, and this in turn potentially has consequences for the well-being of the surrogate mother and the child she carries.

According to some observers, the child's healthy development would seem to depend on the environment provided by the parents and the love they lavish on the child. For others, the permanent abandonment of the child at birth by the woman who brought it into the world is somehow irreparable. This theory of the importance of the early relationship established between mother and child during pregnancy does not meet with universal acceptance, however.

It is important to note once again that while the studies published so far are reassuring, there are still few longitudinal studies devoted to the long-term effects on children resulting from surrogacy arrangements.

According to some psychiatrists, children having to cope with several maternal figures may have difficulty in resolving potential conflicts arising from this situation and may find it difficult to fulfill themselves. Particularly during adolescence, a child resulting from surrogacy may feel a contradictory sense of dual loyalty, on the one hand towards the woman who bore it and on the other towards the intentional parents who wanted it and who consider it as their own.

#### Access to origins

Motherhood can be distributed between two or three women and paternity attributed to one or two men, involving a total of three to five distinct persons in the conception of a child.

In this context, should secrecy be maintained or should the focus be placed on truth about the child's origins? A way should be found to decide whether it is better for the child to be aware of its origins or whether the secret should be kept, while bearing in mind all the implications that such secrecy can have on the child's life.

However, the issue of the secrecy of origins and of anonymity takes on particular dimensions in cases of surrogacy, since it is based on an agreement between parties. A surrogate mother may end up intervening in family life.

#### Women's health

Among the risks to the physical health of the surrogate mother may be noted the possibility of miscarriage, ectopic or multiple pregnancy and medical complications that increase with the age of the mother and the complexity of her reproductive history. A woman is not required to have a child and she can decide not to, but may she legitimately transfer that risk to another woman, especially if she is resorting to surrogacy for non-medical reasons?

The surrogate mother may also be subject to risks to her psychological health. For example, in "handing over the child" she carried to the couple who desired it, she may experience suffering and mourning.

#### Women's autonomy

Surrogacy underlines the idea that the fetus is a being "apart" from the woman carrying it, and this in turn potentially has consequences for the autonomy of the pregnant woman. The Commission is concerned that women who act as surrogate mothers no longer have the autonomy normally accorded to a mother carrying her child. Indeed, prospective parents do not necessarily focus on the well-being of the surrogate mother, but rather on the well-being of the unborn child. And even if prospective parents do show concern about the woman's well-being, how can one be sure that it is as a "surrogate mother" rather than as a person? Moreover, prospective parents may

exert pressures on various aspects of the situation, such as the surrogate's lifestyle, monitoring of pregnancy and childbirth. She must also submit to procedures and examinations offered by the medical team and adopt behaviour conducive to development of a healthy child.

This distinction between the pregnant woman and her fetus is problematic for the whole community, because it calls into question the foundations underlying the right to abortion, and to the integrity, security and autonomy of women. In the Commission's view, reproductive autonomy is established and cannot be questioned, and it is up to the surrogate mother, and to her alone, to take decisions regarding the development of pregnancy, particularly if she eventually signalled her desire to seek an abortion.

Finally, in the event that the surrogate is a friend or sister of an adoptive parent, additional risks of pressure may arise, leading to delicate situations and psychological difficulties for the people concerned. Relationships existing before pregnancy can have positive or negative impacts on the contractual relationship. In addition, unlike the case of a "foreign" surrogate mother with whom parents may decide *a priori* to break off all contact following the child's birth, a surrogate mother who becomes an aunt, or who remains within the close circle of friends of the "adoptive" couple cannot be easily pushed aside after birth. An additional psychological challenge therefore resides in the way relations are managed between the adoptive couple and the surrogate mother, on the one hand, and between the child and the surrogate mother, on the other hand.

#### The non-commercialization of the body and the non-instrumentalization of persons

Surrogate mothers may find satisfaction in helping a couple have a child: the surrogate mother does not derive a direct benefit, beyond the feeling of having helped a couple fulfill their project of having a child. Other women may become surrogates simply for the pleasure of being pregnant. Still others become surrogates in order to make money, while some see it as a way to escape poverty and even to bring some dreams and life projects to fruition. Surrogacy entails the potential exploitation of women, especially of poor women.

In this context, the reimbursement of expenses upon presentation of receipts would have the effect of avoiding the prospect of financial gains, while sparing surrogate mothers the need to bear other pregnancy-related costs on their own. However, making a lump sum payment could discriminate between women, since it could make it seem more advantageous to carry a child on behalf of others than for oneself. Hence the importance for women contemplating surrogacy to be well-informed about the risks they face; to understand that all pregnant women face these risks; while the risks themselves should not easily be assigned monetary values.

In addition to the risk of exploitation of the woman and her body, surrogate motherhood poses a risk to the child who somehow becomes a commodity that can be bought or sold.

#### Cross-border reproduction

Canadians and Quebeckers go abroad every year to procure assisted procreative services that are not available here, or are too expensive. Conversely, and for similar reasons in their country of origin, people living abroad come to Canada. For their part, donors also move from one place to the next, in order to get a better price for their gametes.

Cross-border reproduction (commonly called “procreative tourism”) is disturbing for several reasons: it is only an option for people who can afford it; all control of quality or of security of services offered is impossible – which may pose risks for mothers and children; and it involves and increases the risk that women living in developing countries will be exploited by more affluent foreigners. In addition, since legal prohibitions are generally a reflection of social consensus, it is disturbing that some people circumvent the laws of one country to go to another, where laws are more lax. Procreative tourism also underlies the notion that human reproduction is an object of commerce. The terms “baby business” and “reproductive industry” also illustrate this integration of human reproduction into the domain of commerce.

A question also arises about the responsibility of physicians with respect to procreative tourism. When physicians know that their patients may be tempted to resort to a more open country, should they close their eyes or should they guide their patients towards more acceptable solutions instead? Are they in effect complicit, when making a technical intervention, for example conducting an ultrasound for a woman they know has bought eggs abroad? Can the medical act be dissociated from the whole process of assisted procreation? While doctors have a duty to care for their patients, they should not encourage procreative tourism.

The argument of procreative tourism is invoked each time AP is regulated. The Commission believes that in addition to going against the values of society, easing the laws would do nothing to solve the problem. In Commission’s view, yielding to this temptation is not an acceptable option.

*Whereas surrogacy entails risks of exploitation of women that are ethically unacceptable and considering that such a practice would lead to a form of reification of the child that the Commission cannot endorse.*

*Whereas the prohibition of surrogacy may encourage procreative tourism and thus increase the risk of exploitation of poor women abroad, the Commission contends, however, that this is not a sufficient reason to violate the value of human dignity upheld by Quebec society.*

*Further considering the risks to the autonomy, health and integrity of women, the physical and psychological risks for all actors involved, and considering that surrogacy is a form of instrumentalization and commercialization of the female body and of the human being, the Commission recommends:*

#### **Recommendation No. 10**

That the Government of Quebec maintain the principle of the nullity of surrogacy contracts.

## PREIMPLANTATION GENETIC DIAGNOSIS: MONITORING PRACTICE IN ORDER TO AVOID DRIFT

For many years now, the development of obstetric knowledge and access to certain technologies have been helping people who need medical support to maximize their chances of having healthy children. For example, screening tests for certain diseases are carried out as part of the monitoring of pregnancy; maternal blood tests and ultrasound tests are also undertaken. Additional, more specific tests may be undertaken, such as determining the genetic profile of the fetus. All of these techniques make up what is called prenatal diagnosis (PND).

More recently, a diagnostic method has been developed at a much earlier stage: preimplantation genetic diagnosis (PGD), whose initial objective is to offer an alternative to prenatal diagnosis. Specifically, PGD involves the genetic analysis of cells taken from an embryo derived from *in vitro* fertilization before its implantation in the uterus.

PGD is used in cases of *in vitro* fertilization, and occurs at the early stage of development of the embryo before implantation in the uterus. As such, PGD avoids recourse to abortion, whether spontaneous or medical, which may result from PND. However, for people with no fertility problems who would like to access PGD, it inevitably requires invasive and costly infertility treatments.

Both of these diagnostic techniques – PND and PGD – have a potential for much wider uses than other techniques currently available. PGD first appeared in the 1980s, but preimplantation genetic diagnoses were undertaken on a broader scale in the 1990s. Even though PGD is available everywhere in the world, its practice is still fairly limited.

### The technique: two main objectives

At the present time, PGD is used to undertake two major types of genetic analysis, in order to ensure better outcomes for IVF:

- the karyotype, that is to say, the study of chromosomes, which can detect abnormalities in the number of chromosomes (as in the case of trisomy 21) or in their morphology, and also to identify the sex of the embryo (XX or XY); maternal age (35 and older) is the most common reason invoked for undertaking this analysis;
- diagnosis of DNA molecules by amplification, which is undertaken to identify monogenic inherited diseases, whether they be autosomal recessive disorders (for example cystic fibrosis or mucoviscidosis and spinal muscular atrophy), autosomal dominant disorders (such as Steinert's disease or myotonic dystrophy and Huntington's disease) or recessive X-linked disorders (such as Duchenne muscular dystrophy and X-linked myotubular myopathy), transmitted by women, and affecting only men.

In the context of assisted procreation, it used to be customary to undertake PGD in order to check embryo implantability in the mother. However, this practice is tending to disappear, because PGD may damage or even destroy the embryo; the benefits sought (improving the chances of implantation) are no longer considered to outweigh the risks. Screening is still used to assess embryo implantability, but the technique now used is much less risky for embryos.

Although PGD services are available across Canada, only two laboratories in the country are able to undertake preimplantation genetic diagnosis itself. Biopsies are usually shipped to the United States for analysis.

## The regulatory framework

In Quebec, under the new law on assisted procreation, PGD can only be performed in a centre for which a licence has been issued by the Minister of Health and Social Services, as is the case for all assisted procreation activities. The conditions and standards for these activities are not yet known; they will be established by regulations in the near future, and it is reasonable to expect that the centres authorized to practice PGD will have to implement standard operating procedures. For its part, the Canadian law on assisted reproduction does not expressly mention PGD, but it prohibits certain uses, including sex selection for non-medical reasons.

Currently, PGD is for all practical purposes banned in countries such as Germany, Austria, Italy and Switzerland, even if no law explicitly mentions it. In most countries of the European Union that have chosen to regulate PGD, its practice is in general limited to the detection of chromosomal abnormalities and to cases where there is a risk of hereditary transmission of a severe early-onset genetic disease which is recognized as incurable at diagnosis. In the United Kingdom, the use of PGD for purposes of “family balancing” is expressly prohibited by law. Other prohibited practices include selecting embryos carrying a disease or abnormality in preference to those lacking such a disease or abnormality (i.e. the voluntary promotion of the birth of disabled children).

The application of PGD for medical reasons benefitting a third person (HLA or immunogenetic typing), an application most commonly referred to the practice known as “designer baby”, was recently legalized in Belgium, Denmark, France, Spain, Norway, Sweden and the United Kingdom. On the other hand, it is strictly prohibited in the Netherlands.

A greater number of European countries have legislated on PGD, but countries on several other continents have also legislated in this area. The practice is subject to regulations for example in New Zealand and also in several States of the federation of Australia, such as the State of Victoria. At the present time, the guidelines of the American Society for Reproductive Medicine govern the practice of PGD in the United States. This association endorses neither sex selection for reasons of convenience nor genetic testing for the purpose of increasing the success rate of IVF, given the results obtained.

The PGD regulatory framework is thus derived from many sources. In North America, it involves more self-regulation, whereas in Europe there is a greater tendency to establish a legislative or regulatory environment. While there are many different positions regarding the legitimacy of PGD, there is nevertheless consensus about limiting the practice to medical indications. These indications are however subject to different interpretations in each country, which leads to the conclusion that there is a plurality of positions on PGD.

## General reflections on the use of PGD

Preimplantation genetic diagnosis is now offering applications that generate debate. For some people, any use of PGD can be ethically justified in terms of the reproductive autonomy of individuals and protection of the child's or the community's welfare, especially when genetic diagnosis aims to avoid suffering and the costs of certain genetic diseases or abnormalities. For others, PGD and the selection of genetic traits are unacceptable, whatever the reason invoked, since genetic selection is related to the quest of the perfect baby and to a liberal form of eugenics. Both these positions are extreme, however, and most views are situated in an intermediate zone where the acceptability of PGD use is determined based on the context and the nature of the reasons motivating such use.

### The change in the meaning of assisted procreation

Originally, PGD was developed because it could help avoid the use of PND and forestall the decision to abort which could result from PND. Nowadays, preimplantation genetic diagnosis is being offered on an ever-broader scale, not only to people who need medical assistance to conceive, but also to single people or couples, whether fertile or infertile, who want the benefit of such a diagnosis for embryo selection (whether because they know they are at risk of transmitting a genetic disease, or because they have a seriously ill child, etc.).

This broadening of the reasons justifying access to assisted procreation is somehow changing the meaning of AP, which is now becoming seen as a way to select an embryo that will become a healthy child or, where appropriate, a child with genetic characteristics sought by its future parents (such as immunogenetic compatibility or gender preference).

The development of PGD raises the burning question of how far it is acceptable to go to meet the desire for a *healthy* biological child or one with specific genetic characteristics.

### The complexity and risks of the procedure

An analysis of issues related to PGD must take into account the complexity and the risk associated not only with PGD itself, but also with the related procedure of IVF. PGD is often presented in certain contexts as an alternative to PND, yet it is not a harmless solution. Resorting to PGD involves physical and psychological constraints that pose risks to all those involved.

For the embryo, the removal of cells as part of the diagnostic technique involves some risk for gestational development as well as development of the child at a later date. For women, the main constraints are related to IVF procedures and their share of risks and inconveniences, whether physiological or psychological.

The medical team may experience significant psychological and clinical problems, when they are witnesses to the tensions felt by the couple or single person, and those around the decision-making process. In the absence of clear guidelines concerning indications and acceptable practices, some professional teams experience discomfort when faced with unusual requests.

Another point worth noting in this respect is that the likeliest outcome of PGD is multiple pregnancy and multiple births, since more than one embryo is implanted to increase the chances the procedure will be successful. Given all the risks and disadvantages PGD poses for the embryo, and the various constraints it imposes on the woman, the couple and the medical team, it is hard to consider it as a accessible solution whose consequences are easy to live with.

#### Innovative character and risk assessment

While the constraints induced by PGD can be identified, it must however be noted that the direct (physical or psychological) consequences flowing from this procedure are hard to assess accurately. To date, not enough PGD procedures have been undertaken to allow a good grasp of all the ins and outs of PGD, a solid understanding of the risks involved and any certainty whether the procedure will work or not.

The Commission therefore considers that the innovative character of PGD should be clearly explained to those who opt for it, including the need to more fully document its risks and consequences, and the fate of surplus embryos that are usually subjected to cryopreservation.

The success of PGD is not guaranteed and medical errors may occur, particularly given the limited time available for analysis (12 to 24 hours). These errors can occur for various reasons, including an unfortunate choice of healthy cells or the opposite, for example, or the existence of an abnormality that is not part of the analysis, and therefore goes undetected. In addition, in the light of current research, it is not yet possible determine whether the samples taken from the embryo through PGD can affect the fetus or the child at a later date.

For all these reasons, many clinics recommend that their clients also seek prenatal diagnosis to confirm the outcome of PGD, despite the additional risks this poses for the fetus and for miscarriage. Parents should definitely be made to understand that PGD does not provide an absolute guarantee against the future development of disease.

The decision whether or not to resort to PGD should always strike a balance between the severity and frequency of risks, on the one hand, and the benefits of selecting embryos for preimplantation, on the other. Whatever the circumstances, it is important that sufficient and adequate counselling be provided to those persons involved so they can make a choice that is truly free and informed, especially if the health of the unborn child is a primary concern. Moreover, appropriate information should be provided on other options at their disposal, for carrying out (or, as the case may be, for not carrying out) their parental project.

*Whereas limited research has been undertaken on long-term monitoring of the health status of children resulting from assisted procreation who have also undergone PGD during the embryonic stage, as well as the innovative character of PGD, the Commission recommends:*

#### **Recommendation No. 11**

- That the Minister of Health and Social Services establish a specific licensing mechanism for approval of centres performing PGD;
- That the Fonds de recherche en santé du Québec (FRSQ) set up a research program for evaluating the risks of PGD for embryos and children resulting from this procedure.

#### **The values at issue in PGD**

The values that particularly concern the Commission de l'éthique de la science et de la technologie in its reflection on preimplantation genetic diagnosis are the health and well-being of children, the dignity of these children, the reproductive autonomy of individuals and the equality of all human beings.

#### **The health and well-being of children**

In ethical terms, what clearly distinguishes assisted procreation from other medical practices is its outcome: the “therapeutic” techniques involved in AP lead to the birth of a human being.

Although the welfare of the child is subject to different interpretations, this value can be understood in the context of AP as one involving rigorous medical responsibility for the safety of diagnostic techniques and for physical risks faced by children resulting from PGD. In addition, the Commission considers that this value is related to a responsibility borne by all actors involved in decision-making about PGD, to ensure that the child resulting from it has the same chances as children conceived naturally with respect to physical and psychological development.

In this sense, the Commission is concerned about the negative consequences of a birth attended by a serious disabling illness, for which no treatment is available and that will seriously jeopardize the quality of life of the child. However, promoting health and well-being does not amount to selecting the most genetically perfect or the highest-performance children. Indeed, a child selected *on account* of such genetic characteristics could become “responsible” for becoming what its parents hoped for, without the parents necessarily being aware of the fact. Promoting the welfare of the child therefore means taking into account the physical and psychological health of the child resulting from PGD. In the view of the Commission, this welfare also means that the child should be allowed to be born in a context that, emotionally, will be most conducive to its harmonious overall development.

## The dignity of the child

In terms of assisted procreation, the dignity of the child refers to two principles that underlie this value and that arise in certain clinical situations, most often in connection with requests from people who want a preimplantation genetic diagnosis. These two principles are the non-instrumentalization of human beings and respect for symbolic freedom.

With regard to the non-instrumentalization of human beings, the Commission endorses the principle that the human being should be an end in itself; it should never be considered solely as a means to an end. Concerning PGD, this means that embryo selection should not be viewed primarily as a means to meet special needs. This principle of non-instrumentalization is particularly threatened when PGD is undertaken in order to select an embryo that has a compatibility enabling it to be a donor, usually for an already specified purpose. In this situation, the child is born *because* it is compatible, and it is selected *in order* to be a donor.

The symbolic freedom of a being refers to the lack of predetermination in the direction the life project of each human being takes. In the case of PGD aimed at the health of the child, it is not clear that the symbolic freedom of the child is endangered, as such, although the argument of the slippery slope underscores the deterministic potential caused by advances in human genetics. In the case of diagnosis for the voluntary birth of a child with a disability, for example, it is clear that the child will have to assume a decision taken by its parents and the possibly serious consequences stemming from this decision. Furthermore, the risk of eugenic drifts or of limiting the symbolic freedom of beings resulting from PGD is cause for concern, especially given the development and improvement of diagnostic practice. As technology continues to evolve, it is conceivable that the identification of new genes would incite prospective parents to seek embryo selection, based on genetic discoveries and according to subjective preferences, which could be influenced, possibly in an insidious fashion, by a kind of social norm.

## Reproductive autonomy

The value of reproductive autonomy of individuals and couples is defined as the ability of a person or couple to decide whether to reproduce or not and whether to resort or not to various available means in fulfilment of a parental project. The development of diagnostic techniques and expanded indications of preimplantation genetic diagnosis raise questions, however, about whether the free choice of individuals is respected in all situations. Indeed, it seems that certain parental requests are challenged by values such as respect for the dignity of the child and protection of its welfare and respect for equality among people. These situations create real value conflicts.

In terms of reproductive autonomy, PGD challenges the scope of that value and poses an ethical issue: how far should we go in recognizing the private nature of the decision of couples or individuals to resort to embryo selection on the basis of genetic analysis? Should the severity of disease be defined only for couples? Is reproductive autonomy unlimited? If reproductive autonomy has limits, what are they and how can they be justified ethically?

In the context of reproductive health, private decisions reach a limit when they are likely to hinder the autonomy of a person very closely involved in the situation: the child. Given the opportunities and risks posed by PGD, promoting the reproductive autonomy of couples comes with a significant requirement: it requires that the procedure is resorted to, on the basis of on a free and informed decision.

Although people starting PGD are physically and mentally healthy and capable of making rational decisions, they are nonetheless subject to some form of vulnerability. Professionals monitoring such requests have the responsibility to assess to what extent the desperate character of certain situations may compromise the judgment of these people.

### **Equality among people**

Respect for human dignity requires that equality among all people be recognized. All human beings are born equal, and this fundamental principle is the basis of the Quebec Charte des droits et libertés de la personne (the Quebec Charter of Human Rights and Freedoms) and the Canadian Charter of Rights and Freedoms. Equality among persons is mainly relevant to reflection about preimplantation genetic diagnosis because of the possible consequences of selecting embryos with a view to preventing the birth of persons with particular diseases or carrying particular susceptibility genes.

Knowing that it is possible to diagnose a genetic disease, it is all-important to ensure that children born after such a diagnosis are not stigmatized, that support services offered to their parents are not reduced and that the integration of these people in society is not compromised. Similarly, some authors and caregivers are concerned about the possibility of a form of long-term stigmatization of people with such diseases. Furthermore, if PGD is becoming more efficient and more affordable, will a lot of research still be conducted on the treatment of genetic diseases?

Given the development and improvement of PGD, the Commission fears an eventual increase in social intolerance towards patients or people with severe disabilities. Could the very possibility of avoiding the birth of seriously ill persons or carriers of defective genes or susceptibility genes contribute to an increasingly demanding social redefinition of normality? Moreover, don't universal screening programs pose an indirect challenge to the value of equality among people by suggesting that society is willing to deploy significant resources to prevent the birth of people with a particular disease? Ultimately, embryo selection raises fears associated with any eugenic practice.

### **Practice and ethical issues**

PGD is considered a very early-stage PND, since it analyses the genetic heritage of one or two embryonic cells on day three of their development in order to transfer only healthy embryos. At the present time, these latest applications are steering away from the objectives and indications of PND and are generating the most ethical discussion. These applications aim to: increase the chances of successful IVF, ensure the health of the child, seek to benefit a third person, satisfy non-medical indications. In fact, however, clinical situations often make it hard to distinguish between these applications.

### Diagnosis aimed at increasing the chances of assisted procreation succeeding

It is worth remembering that in all *in vitro* fertilization, embryos are selected on the basis of observations to identify the embryos most likely to develop after implantation and to increase the chances of assisted procreation succeeding.

PGD could improve this selection by identifying embryos that are carriers of an abnormal number of chromosomes, resulting in the majority of cases in implantation failure or miscarriage. As a result, PGD could increase the chances of assisted procreation succeeding. This possibility remains open to debate, however, particularly regarding the benefits of using this technique in women who have experienced multiple miscarriages, have met with failure in previous AP attempts, or are at an advanced age. Several professional organizations agree that more research is needed to determine the true benefits and indications of this type of PGD use. Apparently, other procedures are currently in development which involve less risk to the parties concerned and do not require the removal of cells(s) from the embryo.

When compared to pregnancies resulting from natural conception, pregnancies resulting from IVF are associated with a higher risk of miscarriage, of prematurity (which leads to multiple consequences of varying degrees of severity for the child), of intra-uterine stunting, malformations or congenital diseases. Accordingly, if it proved possible to avoid such risks by undertaking PGD, and if the benefits of such a procedure were confirmed scientifically, then PGD could meet the basic requirements ensuring the well-being of individuals using AP and children resulting from the procedure. However, the Commission is particularly concerned about the prospect that if PGD were to become widespread, it would amount to systematic genetic screening of embryos with abnormalities such as trisomy 21, which raises major ethical and social issues. The Commission therefore stresses the importance of respecting the objectives of PGD, namely to improve the chances of assisted procreation succeeding, and reiterates the need to avoid slippage towards systematic screening of genetic conditions in pursuit of some other objective.

*Whereas PGD for the purpose of increasing the chances of success of AP is not a recognized and proven procedure and considering that current scientific controversies fully justify adopting a prudent approach, the Commission recommends:*

#### **Recommendation No. 12**

That PGD for the purpose of increasing the chances of assisted procreation succeeding be only offered:

- Where specific medical indications are met;
- As part of a research protocol which has been subject to scientific and ethical review.

## Diagnosis aimed at the health of the child

The main objective of preimplantation genetic diagnosis is the detection of genetic diseases or abnormalities with a view to avoiding the birth of children likely to develop diseases after birth. The ethical issues raised by PGD aimed at the health of the child vary, depending on whether monogenic diseases are at stake, recessive diseases, certain disease-susceptibility genes (for example cancer) and late-onset diseases.

### *The diagnosis of monogenic diseases*

This model of PGD is intended for couples or individuals who know they are at risk of transmitting a genetic defect to their children that causes genetic disease. PGD can be used to diagnose major monogenic diseases such as cystic fibrosis (or mucoviscidosis), spinal muscular atrophy, myotonic dystrophy (or Steinert's disease) and sickle cell anemia. The following sex-linked diseases may also be screened: Duchenne muscular dystrophy, hemophilia, adrenoleukodystrophy and Hunter syndrome.

A PGD procedure that makes it possible to select embryos not carrying the gene for a monogenic disease and to implant them into the uterus acknowledges the value of the child's well-being and the concern to respect the reproductive autonomy of individuals. This clinical intervention can prevent an unborn child from living with a disease that could significantly affect its quality of life. The Commission is motivated by a desire to strike a balance between the values of the child's well-being, individual liberty, dignity and the equality of persons, and accordingly proposes looking for a solution:

- that limits access to PGD, which would be offered to parents at risk of conceiving a child with a severe monogenic disease involving irreversible handicaps for the child;
- that offsets access to PGD by a strengthened commitment to ease the integration of persons with disabilities or suffering from these serious diseases, by means of social policies protecting their rights and promoting their integration into society.

It is no easy task to objectively determine the medical indications likely to justify PGD, since such a determination involves the concept of quality of life. As a way of mitigating the subjective nature of this concept, the Commission uses some inclusion criteria for determining which diseases are considered as medical indications for PGD: the severity of disease, its inevitability, its generally severely debilitating or fatal character, and the absence of treatment. This list of criteria is not exhaustive and some borderline cases may arise.

The existence of PGD raises the question about a parents' hypothetical *duty* to select embryos not carrying a disease, and therefore about their responsibility in this regard. Is it the responsibility of parents, clinicians or the State to determine the ethical acceptability of PGD, to specify indications and to select an embryo to be implanted? In the Commission's view, it is clear that society is involved and should therefore take part in these decisions.

*Whereas the collective determination of medical indications for PGD would ensure a balance between the privacy of a parental project, the responsibility of the parties with respect to the health and well-being of the child as well as respect for the equality and dignity of persons, the Commission recommends:*

### **Recommendation No. 13**

That access to PGD be open to couples or individuals with a known risk of conceiving a child with a serious, severely debilitating or fatal inherited monogenic disease, for which there is no known treatment.

*Also whereas it is difficult to determine how far the criterion of severity may be extended, without detailed consideration, the Commission recommends:*

### **Recommendation No. 14**

That the Minister of Health and Social Services grant a mandate to the Agence d'évaluation des technologies et des modes d'intervention en santé (AÉTMIS) to draw up a list of serious, severely debilitating or fatal monogenic diseases, for which there is no known treatment.

Moreover, while medical indications seem to justify embryo selection as a way of avoiding the birth of seriously ill children, a balance must be sought between respect for the dignity of persons living with disabilities and respect for the reproductive autonomy of prospective parents, including the possibility of preventing the birth of a child whose quality of life would be greatly and permanently diminished. It is therefore necessary to consider the possibility that a definition of PGD accessibility criteria could lead in the mid- or long-term to a certain collective standardization of the selection procedure for PGD access. The question of the social consequences that such criteria could have on indications at diagnosis go to the heart of debates about liberal eugenics – a form of discrimination against persons with long-term disabilities, and which would result from a standardized process of embryo selection.

*Whereas risks are associated with open access to PGD for specific medical indications, the Commission recommends:*

### **Recommendation No. 15**

That the Government of Quebec, in order to avoid eugenic practices, as well as discrimination against and stigmatization of people with genetic diseases or genetic abnormalities, improve and set up programs:

- To meet their needs and those around them and
- To promote the integration of these persons into society.

#### *The diagnosis of embryos that are heterozygous carriers of genes for a recessive disease*

While the Commission considers that it is acceptable to make PGD available in cases where the child may develop a serious genetic disease, it does not consider the diagnosis of embryos that are heterozygous carriers of genes for a recessive disease to be an equally acceptable justification for PGD. This diagnosis would be aimed at rejecting embryos carrying a recessive genetic mutation, that is, embryos not at risk of developing the disease after birth.

Yet, is it ethically acceptable to undergo PGD, for the primary purpose of rejecting such embryos and knowing they are unlikely to develop the disease? These children will not live with a serious, incurable and disabling illness. They will have to make reproductive choices in adulthood, in the event that their spouse also carried the same genetic abnormality, but they will have access to PND and eventually to PGD, or may be able to seek alternatives such as adoption or gamete donation.

*Whereas this is a situation where the costs outweigh the benefits that would like accrue to society as a whole and to individuals from such an indication for PGD, the Commission recommends:*

### **Recommendation No. 16**

That access to preimplantation genetic screening not be permitted for the sole purpose of screening embryos that are heterozygous carriers of a recessive disease, that is to say, in cases where one parent is a heterozygous carrier of such a disease.

#### *The diagnosis of susceptibility genes*

The analysis of susceptibility genes aims to identify embryos with a gene predisposing them to develop a disease during their lifetime.

The child carrying the susceptibility gene will not necessarily suffer from the disease in question, because these diseases are multifactorial, that is they are not only caused by a genetic predisposition, but result from a combination of several genes and factors such as the environment, diet, smoking and other lifestyle habits.

This is therefore a matter of screening rather than of diagnosis, since the idea is not to be *certain* that the child will actually have the disease, but rather to *estimate the risk* that the child will develop the disease in adulthood. Alzheimer's disease is often mentioned in this category.

The ethical acceptability of this form of PGD will depend on the justification for resorting to embryo selection, taking into account the *risk* of developing serious illness. According to current thinking, it is more probable that multifactorial diseases will be prevented by adopting healthy lifestyles in a healthy environment than by using PGD to screen for susceptibility genes.

*Whereas in the present state of knowledge, this type of disease – including some cancers such as breast cancer – cannot be classified in the same category as diseases constituting indications for PGD, the Commission recommends:*

### **Recommendation No. 17**

That preimplantation genetic diagnosis not be used to screen an embryo with susceptibility genes to multifactorial diseases.

#### *Diagnosis for the benefit of the health of a third party*

A recent application of PGD consists in developing an *in vitro* embryo, which on the one hand is not a carrier of a genetic disease and on the other is selected for histocompatibility lymphocyte antigen (HLA), so that it is immunologically compatible with a brother, sister or sick relative whose survival depends on marrow or stem cells extracted from umbilical cord blood. In the case of this application, the indication for PGD is the desire to conceive and select an embryo destined to become a donor, hence the designations “designer baby”, “saviour child”, “donor baby”, or “double hope baby”.

Since the chances of success are very slim, couples often have to go through several cycles of *in vitro* fertilization. Moreover, for this procedure to succeed (it requires the birth of a compatible donor), the sick child needs to be able to survive long enough for the IVF procedure to be performed and the pregnancy to be carried to term (minimum one year).

In the context of this type of indication for PGD, the question arises whether the implanted embryo is selected solely because it will not develop serious illness, but also because it has a genetic characteristic making it suitable as a donor of cells from cord blood cells or bone marrow for the benefit of a family member.

The main concerns expressed about the welfare of the child arising from this practice include, among others, its psychological development and its identity. In this situation, the Commission places the values of dignity and respect for the symbolic freedom of the child at the core of its reflection, and also highlights the negative physical and psychological changes that may affect the actors involved.

From the outset, conceiving a child in order to meet the therapeutic needs of a family member necessarily constitutes a form of instrumentalization; the Commission cannot support such a practice. The Commission believes that approving of this kind of “reparative medicine” would amount to allowing for the production of human beings without any consideration for their dignity.

The selection of embryos based on their immunogenetic compatibility also runs the risk of undermining the symbolic freedom of the child: in such cases, the resulting child would be “determined” by the willingness of its parents that it assume a specific role, which constitutes a violation of its physical integrity.

Due consideration should also be given to the psychological risks for the child and for the construction of its personality, when it has been conceived in fulfilment of a “therapeutic” role which its parents want it to play in its family. How will the child perceive itself? What happens if it is not successful in playing the therapeutic role assigned to it? What seems especially threatening in this practice is that this human being carries the psychological burden within the family of representing THE therapeutic solution to a desperate situation.

Physical discomfort may also occur. Insofar as the donation of cells from cord blood involves no risk or discomfort for the infant, the question of the subjection of the designer baby arises more on the mid- to long-term if it were deemed necessary to remove more bone marrow.

*Whereas there are risks to the value of respect for the dignity of the child and its welfare, as well as physical and psychological risks to stakeholders, and whereas the bank of umbilical cord blood managed by Héma-Québec is a promising alternative to help sick children, the Commission recommends:*

#### **Recommendation No. 18**

- That the use of preimplantation genetic diagnosis for the selection of embryos be prohibited where the primary motivation is to conceive a donor of tissue or stem cells;
- That the collection of umbilical cord blood be encouraged in order to supply the public bank managed by Héma-Québec.

#### **Diagnosis for non-medical reasons**

Non-medical reasons prompting people to resort to PGD are: wanting a child with a particular disability, sex selection of a child or ensuring that it is born with specific characteristics.

##### *The birth of children with disabilities*

Preimplantation genetic diagnosis allowing the selection of embryos carrying an illness or disability aims to satisfy the wishes of those who are themselves suffering from this disability or illness, and who want to share this health status with their child. The Commission has focused particularly on the case of a couple of deaf women who made every effort to conceive a deaf child through self-insemination using sperm from a deaf donor. This situation was not an indication for PGD. However, it is quite possible that clinics performing PGD receive requests of this sort, and that clinical teams suffer some discomfort as a result. This choice was based on a current of thought according to which deafness is not a handicap, but is rather a cultural identity.

This parental choice would only be acceptable if it were based on the well-being of the child. Yet, if parents believe that the welfare of their child necessarily depends on being part of the family unit and the existing culture with respect to the disability in question, then it is difficult to deny them access to genetic selection on the basis of disability. The child, however, may be locked into a difficult psychological or existential paradox: if the child does not accept the state chosen for it by its parents, then it denies its own existence. This paradox is all the harder to bear, since it results from a deliberate parental choice.

The Commission recognizes that requiring couples or individuals using PGD to have only healthy children would amount to a new form of State eugenics which the Commission cannot endorse. Such a practice would be contrary to the values of equality and respect of human dignity to which the Commission fully subscribes.

Given the complexity of the problem and to need to reconcile conflicting values, the Commission believes nonetheless that access to PGD should not be offered to couples who from the outset seek to give birth to a child with a disability, while no restriction should be imposed on the genetic status of implanted embryos, once PGD has been performed.

#### *Sex selection*

Some parents use PGD in order to choose the sex of the child when they are carriers of an X-linked disease, such as hemophilia, which develops most often in boys and more rarely in girls. In such cases, sex selection is motivated by purely medical reasons. However, the Commission considers that the possibility of choosing the sex of a child for cultural, personal, or socio-economic reasons is an entirely different matter.

There does not seem to be any consensus in this area. Some people hold that sex selection for non-medical reasons should not be encouraged, whereas they deem it acceptable to sort sperm for the purposes of “family balancing”. It should be noted that American clinics appear to offer the service of sex selection for non-medical reasons, but only to people using PGD for medical reasons; sex selection is thus presented as an additional option.

#### *The choice of specific characteristics*

The Commission wonders about the issue of selecting embryos with certain characteristics particularly favoured by prospective parents. This type of selection is sometimes referred to as production of “customized babies”, given the subjective nature of indications. The choice may involve physical or psychological traits. Science does not seem able to meet these expectations for the time being, but it is clear that some demand for the selection of genetic characteristics based on reasons of so-called convenience could develop in the future.

For the Commission, the conception of human dignity is undermined by the prospect of a world where parents choose the physical and psychological traits of their child. The prospect of such selection reflects the fact that instrumentalization of the unborn being clearly depends on the parental wish to select a child that satisfies their desire.

*Whereas preimplantation genetic diagnosis for non-medical reasons is unacceptable ethically, because it conflicts with respect for the symbolic freedom of the child, and opens the door to choices about specific characteristics that may not pose a risk to the health and well-being of children, but nevertheless would undermine human dignity, the Commission recommends:*

#### **Recommendation No. 19**

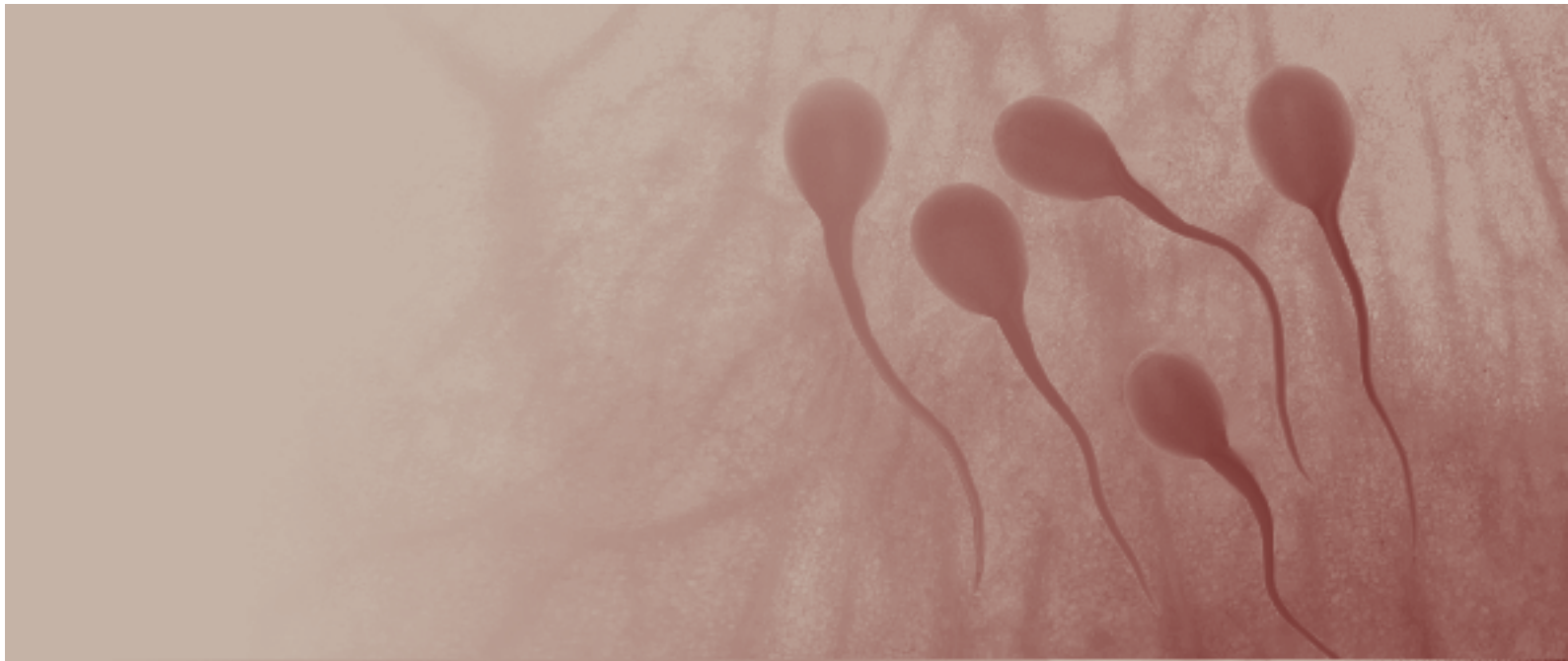
That the use of preimplantation genetic diagnosis be prohibited for the production of “customized babies”, based on non-medical indications, *and that* the use of preimplantation genetic diagnosis be prohibited:

- When the goal is the deliberate production of a child with disabilities or handicaps;
- When sex selection of a child is based on cultural, religious, personal or socio-economic reasons.

In a society that values autonomy, freedom of choice, and that emphasizes individual rights, questioning the legitimacy of the requests that citizens make of the State can be a delicate matter. Even so, this is precisely what the Commission has had to do, in the present position statement, in fulfilment of a mandate entrusted by the Quebec Minister of Health and Social Services. In the field of assisted procreation, the requests of infertile people or of those carrying genes for inherited genetic diseases are often perceived as distress calls. It should be noted that from the point of view of people articulating the desire to have children, this desire can easily become a fundamental need. While considering that having children is a privilege rather than a right, the Commission expresses its empathy for people who encounter significant problems conceiving naturally, without medical assistance. However, as moving as the requests for medical assistance may be, they must also be acceptable in societal terms. This is why the Commission has drafted recommendations and is offering guidelines which in ethical terms serve the public welfare; not all recommendations or guidelines will be universally approved, but the line of argument offered by the Commission may nevertheless contribute to public debates.

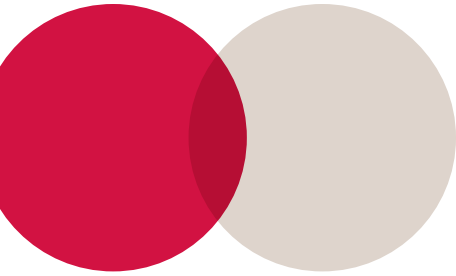
Each of the three issues discussed – gamete and embryo donation, surrogacy and preimplantation genetic diagnosis – could form the subject of a position statement on its own. Other issues would have profited from more detailed discussion, such as *in vitro* fertilization, prenatal diagnosis, eugenics, and filiation, just to name a few. The Commission hopes, however, that this position statement will contribute to advancing reflection which is now needed more than ever, and to inform Quebec legislator on the matter.







INTRODUCTION



## INTRODUCTION

The primary mission of the Commission de l'éthique de la science et de la technologie is to foster reflection on ethical issues<sup>\*1</sup> raised by developments in science and technology, and to propose general guidelines for stakeholders to refer to in their decision-making. The major part of its mission is therefore upstream of the practice of applied ethics and the different forms it takes, these latter being more likely to guide its intervention in the development of regulatory frameworks. The Commission plays the role instead of informing the general public and various decision-makers in order to stimulate discussion as well as open and pluralistic debate on ethical issues associated with a given scientific or technical activity.

With this in mind, the Commission addresses the question submitted to it by the Minister of Health and Social Services (through the Minister of Economic Development, Innovation and Export Trade, to whom the Commission reports), that is, to undertake a “thorough analysis of the ethical and societal

values associated with” assisted procreation\* (AP).<sup>2</sup> In the present position statement, the Commission is analysing the ethical issues related to the development of this scientific field, stimulating public debate and finally making recommendations about the ethical issues raised by AP.

Given that AP is an extensive field of practice and research, the Commission is not able to address all aspects associated with it, in the space of the present position statement. Moreover, in view of the mandate entrusted to it, the Commission's reflection has a specific purpose: to enlarge on work already underway at the Ministry of Health and Social Services and to present ethical considerations related to three practices: gamete\* and embryo\* donation, surrogacy<sup>\*3</sup> and preimplantation genetic diagnosis\* (PGD).

Another aspect of the ministerial mandate concerns examining these issues “in light of public debates.” This dimension of the mandate has taken the form of a three-part public consultation consisting of an online consultation, a call for submissions and hearings. Accordingly, from September 3 to October 3, 2008, the Commission posted a questionnaire online to which all citizens were invited to respond. A total of 1,066 people responded to some 39 questions on the subject. A call for public submissions was issued in June 2008 and led to the tabling of nine written submissions. Finally, in autumn 2008, three days were devoted to hearings with experts in several fields in Quebec and Montreal. Fifteen individuals or groups of persons were heard. Supporting documentation provides a review of these initiatives and is available on the Commission’s website. The Commission takes this opportunity to thank all persons and organizations who participated in these consultations, and ensures them that their contribution has been of inestimable value to its own reflection.

The practices addressed in the position statement challenge the meaning attributed to a number of fundamental concepts, including the concepts of the family and of filiation. In addition, AP offers techniques involving risks that must receive due consideration. The first chapter addresses these issues. This introductory chapter recalls several historical milestones in the evolution of AP, and seeks to raise awareness about the main techniques used in AP.

The second chapter discusses the first real theme of this position statement: gamete and embryo donation. The Commission has benefitted from the collaboration of experts in the field, describes the current state of practice and the techniques used, and then presents the values such donations put at stake and the ethical issues they raise. Particular attention is focused on four of these issues. The issue of the development of children resulting from a donation provides an opportunity to think about the importance accorded to the genetic bond in filiation as well as to a child’s access to its origins. Another issue,

- 1 Terms accompanied by an asterisk are defined in the glossary at the end of the present position statement.
- 2 The expression “assisted procreation” or AP is used in the present document because it is the one most commonly used in Canada. However other terms such as assisted reproduction (AR), assisted human reproduction (AHR) or medically assisted reproduction (MAR) are used elsewhere.
- 3 The Commission has elected to use the terms “surrogacy” and “surrogate motherhood”, although other terms are also acceptable, such as “substitute mother”.

respect for the dignity of each human being, leads the Commission to take a position on the possible commercialization of eggs and sperm and on the selection of gamete donors. In addition, the Commission examines different types of gamete donation in order to analyse them in ethical terms. In terms of prevention and education, the Commission has considered various avenues that could affect fertility upstream of assisted procreation.

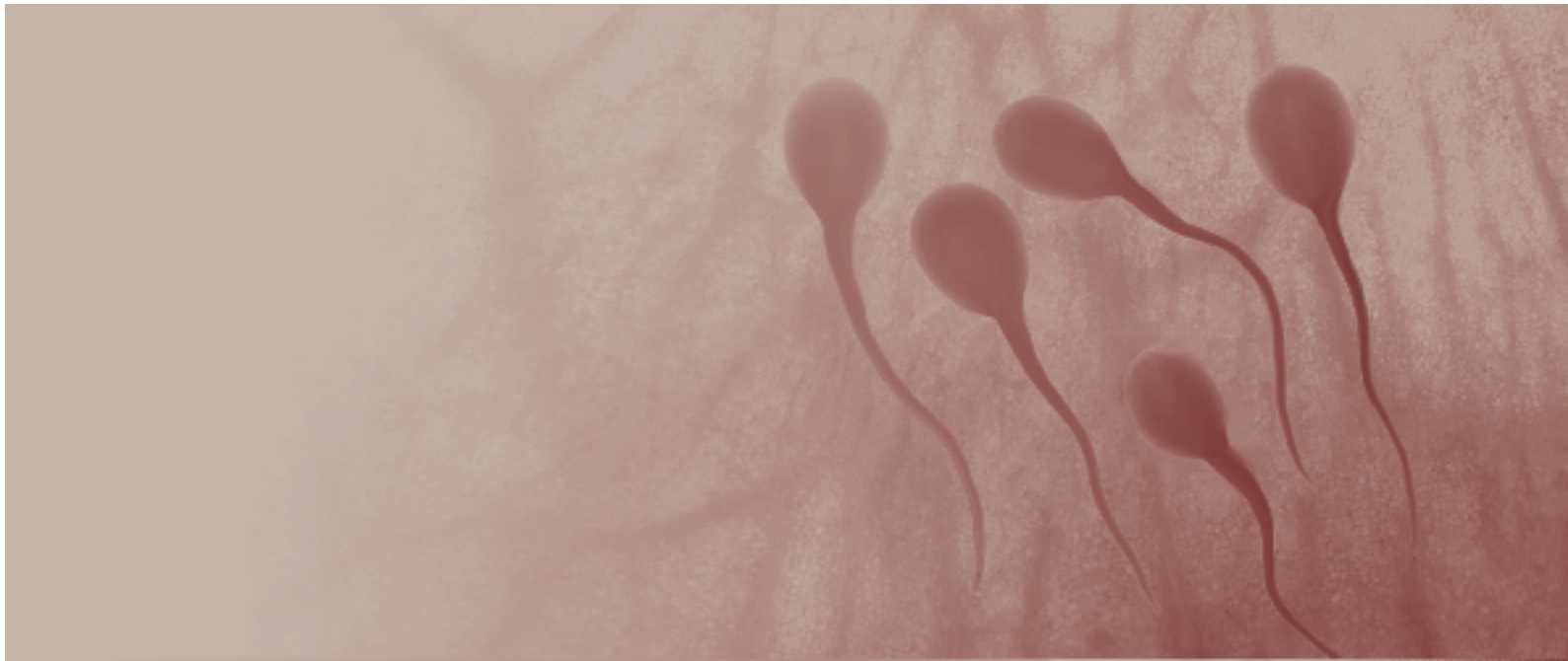
Surrogacy includes situations where a woman continues a pregnancy, not with the intention of keeping the child and taking on the social role of mother, but rather in order to hand the child over at birth to a third party, the “applicant”, whether a couple or a single person. After briefly describing the state of the practice and techniques in this regard, the Commission deals with ethical issues raised by surrogacy: child development, access to origins, the health of women, the autonomy of women, the non-commercialization of the body, the non-instrumentalization of individuals and cross-border reproduction. These considerations are examined in Chapter Three.

The fourth chapter deals with preimplantation genetic diagnosis. This chapter has a somewhat different structure from preceding chapters, and begins with an overview of technology and the regulatory framework, then offers some more general reflections on the use of PGD. This digression is important since it illustrates how PGD contributes in its own way to changing the meaning of assisted procreation. Moreover, it seemed important to emphasize the complexity of this procedure and its innovative character. The Commission also notes that it is hard at present to make a fair assessment of the balance of risks and benefits. Four core values have served as benchmarks in the analysis of PGD, namely the health and well-being of children, the dignity of the child, equality among people and their reproductive autonomy. The ethical issues depend on the objectives sought in performing PGD; each objective is different and calls for fresh analysis, whether the objective be increasing the chances of success of assisted procreation, the health of the child, the health or benefit of a third person, or non-medical reasons.

From the outset, two preliminary remarks should be made: the Commission has kept them in mind throughout the process leading to production of this position statement. First, the Commission considers that, in addition to AP, the adoption of children is an alternative worth considering, in cases where a person is having difficulties conceiving naturally. In addition, the Commission considers that there is no such thing as a “right to a child,” and as a result the State is not required to satisfy the requests of all citizens where assisted procreation is concerned.

The themes related to the beginning and end of life leave no-one indifferent. Assisted procreation is no exception to this trend. AP raises passions and provokes debates, probably because it evokes deep feelings and touches a sphere of human life rich in emotional and symbolic values. However, a clear-sighted analysis of ethical issues requires a more detached and more rational view of practices that are current, or could become current in the near future. One of the challenges the Commission has faced in this position statement lies precisely in striking a balance between the heart and reason. The Commission hopes that its reflection on the ethical issues raised by assisted procreation will make a constructive contribution to current debates on the subject.







THE CONTEXT OF ASSISTED PROCREATION

## THE CONTEXT OF ASSISTED PROCREATION

The term “assisted procreation” refers to various forms of support given to human reproduction using medical or pharmaceutical technologies, or laboratory manipulations<sup>4</sup> that attempt to overcome problems of infertility<sup>5</sup> in heterosexual couples, or the inability to procreate naturally in the case of homosexual couples or single women. These technologies also allow fertile couples for whom there is a risk of transmitting a serious disease, whether genetic or viral,<sup>6</sup> to try to have children who will not suffer from such a disease.

Even when performed because of a medical indication\*, this practice does not aim to treat a pathology (infertility) or the underlying cause of infertility, but rather to address their consequences. Assisted procreation therefore attempts to give concrete expression to the desire for a child despite obstacles or difficulties encountered. In this sense, the medical act performed is of a palliative rather than of a curative nature.

Assisted procreation includes the following activities: ovarian stimulation\* (OS), the collection, processing, *in vitro*\* manipulation and preservation of human gametes, artificial insemination\* with sperm provided by a husband or spouse (AIH) or donor (AID), preimplantation genetic diagnosis, and the conservation and transfer of human embryos.

Although these practices are increasingly seen as routine, safe and effective procedures, they are not risk-free: there are risks to the physical health of women and children resulting from AP;<sup>7</sup> there are psychological risks related to treatment for people resorting<sup>8</sup> to AP or who lend their support, not to mention the risks that these techniques include, in particular the fact that they sometimes fail;<sup>9</sup> and there are risks to the development of children which current data, given their insufficient and methodologically questionable nature,<sup>10</sup> do not make it possible to assess properly. At a more fundamental level, however, assisted procreation has disrupted our symbolic points of reference, our representations of the family and kinship of the child, and of the existence and intrinsic value of the human being.

- 4 This definition is partly derived from the definition in article 2 alinea 1 of Bill 26, passed on June 18 2009 and assented to on June 19 2009: *An Act respecting clinical and research activities relating to assisted procreation*, R.S.Q. 2009, c. 30.
- 5 In general, infertility refers to the state of a heterosexual couple in procreative age who are unable to conceive after a year of unprotected intercourse. (Gilles DESAULNIERS, *L'investigation de l'infertilité*, [online], <http://www.gynecomedic.com/php/infert.php>). Some scientific articles establish degrees of infertility. For example, subfertility is referred to when the time needed to conceive is prolonged. Most pregnancies occur in the first six cycles of unprotected sexual relations during the fertile period of the cycle. Subfertility is said to occur after 12 cycles with no outcome (10 % of couples); the birthrate will however reach 55 % in the following 36 months. After 48 months, approximately 5 % of couples are definitively infertile and have practically no chance of a spontaneous pregnancy. (C. GNOTH *et al.*, "Definition and prevalence of subfertility and infertility", *Human Reproduction*, 2005, vol. 20, n°5, p. 1144). Other authors propose a grading system for fertility; Grade 0: normal fertility (> 60 % chance of conception), Grade 1: slightly reduced fertility (40-60 % chance), Grade 2: moderately reduced fertility (20-40 % chance), Grade 3: seriously reduced fertility (0-20 % chance), Grade 4: sterility (zero chance) (J.D.F. HABBEMA *et al.*, "Towards less confusing terminology in reproductive medicine: a proposal", *Human Reproduction*, 2004, vol. 19, n°7, p. 1500).
- 6 We are thinking here of serodifferent couples in which one of the partners is seropositive for the human immunodeficiency virus (HIV).
- 7 The most important of these being multiple pregnancy: "Compared to the rate of multiple pregnancies in the general population, which is approximately 2%, the rate of such pregnancies is 20 times higher in IVF programs and 2 to 10 times higher in OS programs without IVF. [...] As a result, the risks for children are respectively 5 to 20 times greater in infertility programs with OS but without IVF, and with IVF." (our translation). See Raymond D. LAMBERT and Marc-André SIRARD, "Sur les conditions d'exercice de la pratique médicale du traitement de l'infertilité et de la recherche connexe", *L'Observatoire de la génétique*, July-August 2005, n° 23, [www.ircm.qc.ca/bioethique/obsngenetique](http://www.ircm.qc.ca/bioethique/obsngenetique). In 2005 in Canada, almost one pregnancy in three resulting from IVF led to the birth of twins and around 1% of these cases to triplets. (Joanne GUNBY *et al.*, "Assisted reproductive technologies in Canada: 2005 results from the Canadian Assisted Reproductive Technologies Register", *Fertility and Sterility*, 2009, vol. 91, n°5, pp. 1721-1730). On the possible consequences for children, also see William BUCKETT *et al.*, "Obstetric outcomes and congenital abnormalities after in vitro maturation, in vitro fertilization, and intracytoplasmic sperm injection", *Obstetrics & Gynecologists*, October 2007, vol. 110, n°4, p. 889.
- 8 On the possible consequences for these people, see Lynn Clark CALLISTER, "The pain and the promise of unfilled dreams: Infertile couples", in D. Russell CRANE and Elaine S. MARSHALL (eds.), *Handbook of families and health – interdisciplinary perspectives*, Sage Publications inc., 2005, p. 99.
- 9 According to report presenting the results of the Canadian registry of assisted procreation in 2005, of 11,414 cycles where an AP technique was involved, 3,443 (or 30.2 %) resulted in a pregnancy and 2,713 (or 24.0 %) in a birth (2,687 or 23.8 % in a live birth). For an analysis of the problems encountered by couples or individuals resorting to AP, see P. REVIDI and B. BEAUQUIER-MACCOTTA, "Problématiques psychiques dans les aides médicales à la procréation", *Pédopsychiatrie*, 2008.
- 10 P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.*

## FROM ADULTERY TO THE DESIRE FOR A CHILD OR TO THE RIGHT TO A CHILD

In the eighteenth century, experimental biology first explored assisted procreation as a way of overcoming male infertility.<sup>11</sup> Since that time, AP has continued to develop discretely in medical practice. From the outset, using technological means to assist reproduction has raised moral issues, particularly with regard to sexual morality. It should be noted that the fact a third party intervened in the sexual intimacy of a couple, even when this party was a physician, was at the time considered morally unacceptable.<sup>12</sup>

Also, the use of donor sperm in some cases of male infertility, a practice which developed in the early nineteenth century,<sup>13</sup> only increased the extent of moral disapproval, which in turn had the effect of pressuring physicians to act in secrecy or at least with discretion.

Nowadays, assisted procreation has a recognized and institutionalized place, which has allowed many people to fulfill their desire to have a child. Moreover, it has become a major and highly profitable activity in several countries,<sup>14</sup> and has become widespread in large part due to the development of new technologies, including that of *in vitro* fertilization\* (IVF), which has helped overcome female infertility, and the freezing of gametes and embryos for future use. Thus, since 1978, with the birth of Louise Brown, resulting from IVF<sup>15</sup> – the first “test tube baby” – more than one million children worldwide have been born as a result of this fertilization\* technique.<sup>16</sup> But the growth of AP use, in turn, also contributes to the emergence of new societal values and of social changes shaping those values.

There is no need to dwell in this position statement on the various developments and changes in the social representation of AP. However, the Commission considers that the technical means and standards that physicians have adopted, in order to meet the moral judgments of their time, have contributed greatly to this evolution. The involvement of a third person in the conception of a child could be seen as a form of adultery, and physicians have therefore developed technical measures so that medical practice cannot be equated with morally unacceptable sexual behaviour. The medical profession has also sought to establish and enforce a regulatory framework which could limit the impact of assisted reproductive technologies (ART) on family lifestyles. The notion of medical indications seems to have made the transition possible between, on the one hand, applications considered socially and morally acceptable and, on the other, applications likely to destabilize social life and an individual’s emotional and mental equilibrium.<sup>17</sup> In addition to promoting the social acceptance of ART, this concept has also helped transform the AP activities into an “infertility therapy.”

The notion of medical indications has provided a point of departure for lawmakers, in setting legal frameworks for the drafting of laws and practice guidelines. However, with the exception of certain countries such as France<sup>18</sup> and Germany, the concept of medical indications is no longer the primary justification for access to AP. Indeed, in Canada and Quebec, as in many other countries, access to AP is not only associated with a diagnosis of infertility; it is associated more broadly with the desire to have a child. Infertile couples still form an important segment of the client base of fertility clinics, but more and more services are now offered to single women and homosexual couples.

Gradually, this desire to have a child has increasingly been transformed into a “right to a child,” which in turn includes the right to use all available means to have a child. While the desire for children is legitimate, it is important to consider whether to respond to individual desires at any cost, or whether to give precedence to the public welfare. This question is central to the whole issue of AP, since some people consider infertility to be part of the private sphere, rather than the public sphere. Responding to a large number of these individual desires could also have serious implications for the financing of the health-care system for society as a whole.

- 11 As Laurence TAIN notes, the first known artificial insemination leading to a birth took place in 1776, and was shrouded in complete secrecy: “the husband, an English draper, practiced insemination with the husband’s sperm, using a heated syringe; Doctor Hunter was present, gave his instructions and the report of this event was only published by the Royal Society in 1799, by which time Hunter had already been dead for six years.” (Laurence TAIN, “Les nouvelles techniques de reproduction, nouveaux acteurs, nouveaux enjeux”, *Informations sociales*, 2005, n° 128, p. 53) (our translation).
- 12 Simone NOVAES, “Procréation assistée”, in Monique CANTO-SPERBER (ed.), *Dictionnaire d’éthique et de philosophie morale*, Paris, Presses universitaires de France, 2001, p. 1262.
- 13 This first insemination using donated sperm took place in 1884. This technique was developed during the first half of the 19<sup>th</sup> century, but quickly met with public disapproval. The condemnation of this technique by the Catholic Church played a part in this disapproval. See Christian BYK, “Les situations limites méritent-elles un droit ?”, *Médecine et droit*, 2006, n°77, p. 48; P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.* In Canada, this technique only began to be performed in the 1950s.

- 14 In the United States alone, AP is a US\$3 billion industry. (Nancy GREEN, “The baby business: How money, science, and politics drive the commerce of conception”, *Journal of Clinical Investigation*, Book review, 2006, vol. 116, n° 8, p. 2061, [online], <http://www.jci.org/articles/view/29554>).
- 15 Two British researchers developed this technique for human use: the biologist Robert EDWARDS, and the gynaecologist Patrick STEPTOE. See Patrick C. STEPTOE and Robert G. EDWARDS, “Birth after the Reimplantation of a Human Embryo”, *The Lancet*, 1978, vol. 2, n° 8085, p. 366.
- 16 “It should be noted that there is not a lot of data on the use and outcomes of AP in Quebec. When the bill was tabled in the Quebec National Assembly, the minister estimated that around 1,700 fertilization cycles started each year and about 600 births resulted from AP treatments. The exact number of children is not known however, since it is possible that the physician monitoring the pregnancy may not be aware that the pregnancy resulted from AP techniques.” (CONSEIL DU STATUT DE LA FEMME, *Mémoire sur le projet de loi n°89, Loi sur les activités cliniques et de recherche en matière de procréation assistée et modifiant d’autres dispositions législatives*, Québec, March 2006, p. 15) (our translation).
- 17 Simone NOVAES, *op. cit.*, p. 1263.
- 18 When French bioethics laws were being revised, this question was the focus of debates during the États généraux, in which French citizens were invited to participate. See Alain GRAF, *Rapport final sur les États généraux de la bioéthique*, July 2009 and CONSEIL D’ÉTAT, *Les études du Conseil d’État : La révision des lois de bioéthique*, Paris, La Documentation française, 2009.

## TODAY'S TECHNIQUES ARE MORE EFFECTIVE BUT ALSO INVOLVE RISKS

Clinical assisted procreation activities involve many different kinds of procedures; they depend on the cause of infertility or sterility, which prevents conception of a child, or on the desire to have a child among people who have no fertility problem,<sup>19</sup> but who cannot procreate naturally. In general, these measures include the following practices:

### CLINICAL PRACTICES IN ASSISTED PROCREATION

- **Ovarian stimulation (OS)** can induce ovulation\* in women who suffer from a lack of ovulation, or improve its quality in cases of abnormal or non-optimal ovulation. It is commonly used in most AP protocols to induce fertility, optimizing the production of eggs from women who have no problem with ovulation.
- **Artificial insemination (AI)** is a method of *in vivo*\* fertilization (intracorporeal insemination) which consists in injecting sperm into the female reproductive system from her spouse (homologous insemination) or that of a donor (heterologous insemination), once sperm quality has been ascertained. It can be used along with, or without, ovarian stimulation.
- **In vitro fertilization (IVF)** is a method of extracorporeal fertilization; once gametes are collected, they are placed in a culture medium in order to facilitate their fusion, after which the resulting embryos are then transferred into the uterus. IVF can be performed using eggs from the woman being fertilized or from a donor, as well as the sperm of her husband or that of a donor. This technique is most commonly used when the Fallopian tubes are obstructed, in cases of unexplained infertility or severe male infertility. When using an egg donation is possible, IVF is also an avenue for women who experienced early menopause or have ovarian failure. IVF is also indispensable for egg donation and preimplantation genetic diagnosis. However, there are different kinds of IVF:
  - **Stimulated-cycle in vitro fertilization** (with ovarian stimulation) is considered standard practice nowadays.

- **Natural-cycle *in vitro* fertilization** does not require ovarian stimulation. This type of IVF has some advantages, such as reduced side effects and lower cost, but additional chances of pregnancy are less likely to arise from it than from stimulated-cycle IVF.<sup>20</sup> In Canada in 2005, this practice was quite marginal: 106 IVF cycles were performed without ovarian stimulation for a pregnancy rate of 11.3% per cycle started, 29.3% per embryo transfer and a live birth rate (all singleton births) of 7.8% and 21.1%, respectively.<sup>21</sup> It is used especially in cases of egg donation between sisters or between friends, because in such cases the recipients want to avoid as much inconvenience as possible to the donor, or in cases where the donor refuses ovarian stimulation.
- ***In vitro* maturation\*** (IVM)<sup>22</sup> is a technique that does not require ovarian stimulation. It is generally proposed to young women who naturally produce several follicles or who are most at risk of suffering from ovarian hyperstimulation\*. Immature oocytes\* are collected and brought to maturity in the laboratory over a period of 24 to 48 hours. Once the eggs mature, fertilization is then carried out and the fertilized eggs are then transferred into the uterus of the female recipient. IVM is still experimental, that is, subject to a clinical trial protocol; about 50 cycles of IVM are undertaken in Canada per year, mostly among women with polycystic ovary\* syndrome.

19 In Quebec, *Le grand dictionnaire terminologique* defines infecundity (in French: *infécondité*) as the absence of live births, for a woman, a man or a couple. Infecundity may be the consequence of sterility or may correspond to a desired situation, as a result of contraception, abortion or even abstinence. For its part, infertility is the state of being unable to procreate. When infertility is definitive, one can then speak of sterility.

20 B. ROSSIN-AMAR, "En fécondation *in vitro* (FIV), pourquoi je stimule?", *Gynécologie Obstétrique & Fertilité*, September 2007, vol. 35, n° 9, pp. 881-884.

21 Joanne GUNBY *et al.*, *op. cit.*

22 In 1991, South Korea saw the first birth of a child resulting from IVM without ovarian stimulation. In 2003, about one hundred children were born resulting from an IVM protocol, mostly in South Korea, Canada and Denmark. This technique has met with mixed results. (INSTITUT NATIONAL DE RECHERCHE PÉDAGOGIQUE, *La MIV ou maturation in vitro des follicules*, [online], <http://www.inrp.fr/Acces/biotic/procreat/amp/html/MIV.htm>).

- **Assisted hatching\*** is a technique used in cases where the thickening of the pellucid zone makes hatching difficult (an embryo<sup>23</sup> that has been transferred into the uterus needs to “hatch” or get out of the pellucid zone or protective shell of cells surrounding the embryo, before it implants itself into the uterine wall). This problem occurs in older women, and following IVM and cryopreservation\* (a means of conserving embryos by freezing them). A tiny incision is made in the pellucid zone with a computer-assisted laser, to allow the cell mass of the embryo to escape more easily.
- **Intracytoplasmic sperm injection\*** (ICSI) involves injecting a single sperm through the outer shell around the egg, using a micropipette (immature sperm<sup>24</sup> may be used for this purpose, although this is rarely done). This technique is generally used in cases where male infertility is sufficiently severe to prevent the sperm from penetrating the shell surrounding the egg or when the egg has a pathology preventing sperm penetration. ICSI can also be used following IVM in order to get a better fertilization rate.<sup>25</sup>
- **Egg vitrification** is an innovative technique allowing women to freeze their eggs for future use; the success rate of this technique is substantially the same as with fresh eggs.<sup>26</sup> Thus, young women undergoing cancer treatment<sup>27</sup> may suffer from infertility or early menopause as a result, and could freeze their eggs prior to chemotherapy and use them once they recover. To date, seven women have successfully conceived using this method and the first baby conceived using a vitrified egg was born in 2005.<sup>28</sup> This technique avoids the use of oocytes from a third person. Although the technique is still in an experimental stage,<sup>29</sup> it is expected to develop further.<sup>30</sup> Vitrification is also beginning to be used in the United States by women who simply want to postpone pregnancy. Vitrification allows them to avoid the risk of not producing enough eggs or of only producing oocytes of lower quality, if they want to be pregnant.<sup>31</sup>

As the Commission has already pointed out, these techniques involve certain risks, and deserve attention, although the Commission’s mandate does not specifically ask for such an analysis.

### **Risks for the physical and psychological health of women and children**

The particular nature of assisted reproductive techniques is that they are located halfway between innovation and experimentation. AP has existed for thirty years, but new ways of doing things are constantly being added to the body of ART. Although data on the physical health of humans can be extrapolated from experiments performed on animals – and sometimes even without prior animal experimentation – the fact remains that there is insufficient evidence on the health and development of children resulting from the most recent technologies, such as IVM and ICSI, on women’s health and on the future of couples using them.<sup>32</sup>

Some risks are now well documented, however. The most important risk is multiple pregnancy, which constitutes a risk to the health of mother, fetuses and unborn children, regardless of the reproductive technique used.<sup>33</sup> In 2005, nearly one in three pregnancies in Canada,<sup>34</sup> resulting from IVF led to the birth of twins and about 1% of pregnancies resulting from IVF led to the birth of triplets.<sup>35</sup> Similar statistics have been obtained in the industrialized countries. It should be noted that the older a woman is, the greater is the decrease in the rate of embryo implantation. Thus, the average age for implantation of four embryos is 39 years, for three embryos 37 years and for two embryos 34 years.<sup>36</sup>

- 23 After the egg is fertilized by sperm, the resulting zygote becomes an embryo. It is generally accepted that the embryonic phase lasts from conception until about the third month of pregnancy, and that the fetal phase lasts from the third month until birth. According to *Le grand dictionnaire terminologique*, the embryo becomes a fetus once it is released from the vitelline envelopes. It should be noted that some people use the term “pre-embryonic” in reference to the first two weeks of pregnancy, that is, before the embryo implants itself into the uterine wall.
- 24 According to the authors of the book *Médecine et biologie de la reproduction*, 12 children were born as a result of ICSI using sperm from patients with azoospermia. It seems however that few people believe in this technique nowadays, which may explain the extremely low rate of implantation. (Samir HAMAMAH *et al.*, *Médecine et biologie de la reproduction*, Elsevier Masson, 2004, p. 284).
- 25 MCGILL REPRODUCTIVE CENTRE, *In vitro maturation - Treatments*, [online], <http://www.mcgillivf.com/e/McGillIVF.asp?page=184.186.212>.
- 26 Formerly, cryoconservation procedures used to involve the use of cryopreservatives that were harmful for cells.
- 27 In addition to cancer, new indications favouring egg vitrification include multiple sclerosis, a risk of early menopause, systemic lupus erythematosus and other auto-immune disorders, women who have had ovarian surgery, those with a genetic disorder such as Turner syndrome and carriers of the fragile X mutation. (Ri-Cheng CHIAN *et al.*, “Obstetric outcomes following vitrification of in vitro and in vivo matured oocytes”, *Fertility and Sterility*, 2009, vol. 91, n° 6, pp. 2391-2398).
- 28 Jadzia JAGIELLOWICZ, “Faire des bébés”, *En tête*, 2005, vol. 1, n° 1, [online], <http://français.mcgill.ca/headway/fall2005/infocus/>.
- 29 Brendan MAHER, “Little consensus on egg freezing”, *Nature*, October 25 2007, vol. 449, n° 7165, p. 958.
- 30 Andrea BORINI *et al.*, “Clinical efficiency of oocyte and embryo cryopreservation”, *Annals of the New York Academy of Science*, April 17 2008, vol. 1127, n° 1, p. 49.
- 31 NEW HOPE FERTILITY CENTER, *Fertility preservation*, [online], <http://www.newhopefertility.com/biological-clock.shtml>.
- 32 For example, it appears that ICSI was developed directly in humans: “When ICSI was introduced as a method for treating human infertility, no study of risks had been undertaken in domestic species and only a few animals had been derived from the procedure.” (Raymond D. LAMBERT and Marc-André SIRARD, *op. cit.*) (our translation).
- 33 Raymond D. LAMBERT, “Safety issues in assisted reproduction technology. The children of assisted reproduction confront the responsible conduct of assisted reproductive technologies”, *Human Reproduction*, 2002, vol. 17, n° 12, pp. 3011-3015 and Raymond D. LAMBERT, “L’assistance médicale à la procréation et son influence sur la prématurité”, *Ethica*, 2003, vol. 15, n° 1, pp. 13-41.
- 34 According to the Canadian Assisted Reproductive Technologies Register, of 11,414 cycles in 2005 involving an AP procedure, 3,443 (30.2 %) resulted in a pregnancy and 2,713 (24.0 %) in a delivery (2,687 or 23.8 % in a live birth). A total of 804 multiple births were recorded (29.6 %) of which 767 were twins (28.3 %) and 37 triplets (1.4 %). (Johanne GUNBY *et al.*, *op. cit.*). See the tables in Appendix 2.
- 35 In the case of triplet pregnancy, the medical team of a fertility clinic strongly recommends fetal reduction to singleton or twins. See MCGILL REPRODUCTIVE CENTRE, *In vitro Fertilization – Risks of Treatment*, [online], <http://www.mcgillivf.com/e/McGillIVF.asp?page=184.186.210#Risk>.
- 36 However, the fact of transferring more than two embryos does not increase the rate of clinical pregnancies. In some cases, more than five embryos may be implanted. (Johanne GUNBY *et al.*, *op. cit.*).

## COMPARISON OF MULTIPLE PREGNANCY RATES BY COUNTRY

Country	Twin pregnancies (%)	Triplet pregnancies (%)
Canada (2005) <sup>a</sup>	28.3	1.4
United States (2003) <sup>e</sup>	31.0	3.2
Belgium (2000) <sup>c</sup>	~ 24	~ 1
France (2003) <sup>d</sup>	26.2 (IVF) and 23.9 (ICSI)	< 1.5
Germany <sup>b</sup>	N/D	2.4
Switzerland <sup>b</sup>	~ 20 (2002)	1.5 (2001)
Finland <sup>b</sup>	N/D	0.2
Europe <sup>b</sup>	26	N/D

### Sources:

<sup>a</sup> Joanne GUNBY *et al.*, *op. cit.*

<sup>b</sup> Theres LÜTHI, “Le problème des grossesses multiples”, *Bulletin des médecins suisses*, 2006, vol. 87, n° 21, p. 943.

<sup>c</sup> P. DE SUTTER *et al.*, “Une décennie d’enregistrement des données de la procréation médicalement assistée en Belgique”, *Revue Médicale de Bruxelles*, 2004, vol. 25, n°3, p. 162.

<sup>d</sup> J.N. HUGUES, “PMA : quoi de neuf?”, *Réalités en Gynécologie-Obstétrique*, May 2008, n°130, p. 1.

<sup>e</sup> Jason K. MIN *et al.*, “Guidelines for the number of embryos to transfer following *in vitro* fertilization”, *Journal d’obstétrique et de gynécologie du Canada*, September 2006, n°182, p. 801.

For the mother, there is also a greater risk of complications during pregnancy, such as hypertension (high blood pressure), diabetes, anemia, pre-eclampsia, the risk of hemorrhage and miscarriage.<sup>37</sup> Although the reasons are unclear, they may be due to several factors, including the age of the mother.<sup>38</sup> For the fetus\*, there is an increased risk of fetal death; for the child, the risks are prematurity, cerebral palsy, developmental delay and low birth weight.<sup>39</sup> However, some observers say that all these complications are not necessarily related to the procedure as such. Infertility could be a risk factor in itself.<sup>40</sup>

Regardless of multiple pregnancy, OS also presents risks to the health of women, the most frequent of which is ovarian hyperstimulation syndrome\* (OHSS), the severity of which may affect women to a greater or lesser degree, for example by inducing nausea, vomiting, abdominal distension and pain, enlarged ovaries, dyspnea (difficulty breathing), kidney dysfunctions or failure.<sup>41</sup> Various studies indicate an increased risk of cancer associated with drugs for ovulation induction, although no clear conclusions can be drawn.<sup>42</sup>

The significant part played by stress and frustration accompanying such a complex technology should also be noted: examples include the medicalization\* of an intimate act, the use of invasive procedures and surgery, the side effects of drugs. Additional examples are medical appointments that interfere with daily life and the obligation of planned rather than spontaneous sexual intercourse.<sup>43</sup>

The risks inherent in the failure of reproductive technologies should also be considered, for people who then have to mourn the failure of their project of having a child:

« [...] the announcement of a traumatic diagnosis, the anxiety of waiting for medically-assisted procreation, the stress at each attempt, and very often the final failure, a little known yet critical moment for couples who must then abandon the hope of having a child, or resort to adoption. The frequency of depressive disorders among sterile women is emphasized, as well as the suffering of sterile people facing guilt-inducing social disapproval.<sup>44</sup>

To this can be added the psychological risks associated with the inability to procreate, the most frequently identified of which are: the loss of sexual and parental identity, the deterioration of the relationship between the spouses, with family members or with friends, depression, guilt, loss of self-esteem and the sense of losing control.<sup>45</sup>

The psychological risks for children are poorly documented to date. The results of studies published so far include reassuring aspects,<sup>46</sup> but these studies are “still insufficient and methodologically questionable.”<sup>47</sup> This issue will be analysed later in the context of ethical issues raised by the participation of third parties to human reproduction.



- 37 Ounjai KOR-ANANTAKUL *et al.*, “Outcomes of multifetal pregnancies”, *Journal of Obstetrics and Gynaecology research*, 2007, vol. 33, n°1, pp. 49-55.
- 38 MCGILL REPRODUCTIVE CENTRE, *In vitro Fertilization – Risks of Treatment*, *op. cit.*
- 39 Raymond D. LAMBERT, “Safety issues in assisted reproduction technology”, *op. cit.*, pp. 3011-3015; Raymond D. LAMBERT, “L’assistance médicale à la procréation et son influence sur la prématurité”, *op. cit.*, pp. 13-41; Ounjai KOR-ANANTAKUL *et al.*, *op. cit.* On neurological problems, malformations and physical deficiency in children, see also William BUCKETT *et al.*, *op. cit.*; Prashant NAIR, “As IVF becomes more common, some concerns remain”, *Nature Medicine*, 2008, vol. 14, n°11, p. 1171.
- 40 Raymond D. LAMBERT, “Safety issues in assisted reproductive technology: Aetiology of health problems in singleton ART babies”, *Human Reproduction*, 2003, vol. 18, n°10, pp. 1987 and 1990.
- 41 Botros RIZK, *Ovarian hyperstimulation syndrome: Epidemiology, pathophysiology, prevention and management*, Cambridge, Cambridge University Press, 2006, pp. 7-8.
- 42 R. CALDERON-MARGALIT *et al.*, “Cancer risk after exposure to treatments for ovulation induction”, *American Journal of Epidemiology*, February 1 2009, vol. 169, n°3, pp. 365-375.
- 43 Lynn Clark CALLISTER, *op. cit.*, p. 99.
- 44 P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.* (our translation).
- 45 Lynn Clark CALLISTER, *op. cit.*
- 46 See, among others, the studies cited by Laurent RAVEZ, *Les amours auscultées, une nouvelle éthique pour l’assistance médicale à la procréation*, Paris, Éditions du Cerf, 2006, p. 55.
- 47 P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.*

## BEYOND MEDICAL INDICATIONS: THE EVOLUTION OF THE CONCEPT OF THE FAMILY AND ITS TRANSPOSITION IN THE LEGAL SYSTEM

Beyond the fact that conception methods have improved, elements contributing significantly to the growing use of AP are the social representations of the family and the desire to have a child with a genetic background representative of its family – even if only partially.<sup>48</sup>

To better understand the general trends affecting the means by which a society reproduces itself, it is important to inquire first into the characteristics which a family needs in order to be regarded as such within a community or group.

At certain times and in certain cultures, a model family was recognized, accepted and promoted as an ideal, but it should be noted that the representation of the family has changed and now takes several forms: stepfamilies, single-parent families and same-sex parents are now social realities that need to be taken into consideration. Although the traditional nuclear family (man, woman and children) is no longer the only socially accepted model, it remains “the dominant model”,<sup>49</sup> according to researchers.

According to a recent Quebec study, the most widely accepted family scenario is that of “two adults – a couple – and a child”;<sup>50</sup> indeed, for 82% of respondents this model meets the definition of a family.<sup>51</sup> However, the vast majority of respondents are still willing to consider other models of the family. Thus, “a mother with a child” (65% of responses) and “a father with a child” (62%) are in fact perceived as families. “Two women with a child” and “two men with a child” may also constitute a family for respectively 50% and 46% of respondents. Researchers cannot rely on a comprehensive sociological analysis of the contemporary family, but they believe, however, that these data reveal the evolution of public opinion vis-à-vis the various forms of family life on the one hand, and maintaining a social representation of the traditional family as the nuclear family, on the other.

The *Act instituting civil unions and establishing new rules of filiation*, which entered into force June 24, 2002,<sup>52</sup> amended certain rules regarding AP and adoption, in order to reflect this societal change and to formally recognize a new family model resulting from homoparentality. Indeed, under the law, two persons of the same sex can now have a child together; the child will have two mothers or two fathers, as the case may be, whether it has been adopted or, particularly where the two parents are women, if the child results from AP.

Previously regarded “as an exception enabling a couple to medically overcome the infertility of one member of the couple,”<sup>53</sup> assisted procreation is now a “means of establishing filiation, in a full-fledged and autonomous manner.”<sup>54</sup> This assistance moreover is not necessarily medical; it may be provided through sexual intercourse or even sperm donation between individuals.<sup>55</sup> It need only be resorted to as part of a parental project as defined in Article 538 of the Civil Code of Quebec to establish filiation: “A parental project involving assisted procreation exists from the moment a person alone decides or spouses by mutual consent decide, in order to have a child, to resort to the genetic material of a person who is not party to the parental project.”<sup>56</sup> This project may be undertaken by a single person – necessarily a woman, since the legislator maintained provisions preventing women from undertaking to procreate or carry a child for others<sup>57</sup> – or by a heterosexual or homosexual couple, but again, the homosexual couple will have to consist of two women. These spouses need not be married or in a civil union; they may include *de facto* spouses.<sup>58</sup> In each case, the child’s filiation will be determined in the same manner as filiation by blood.<sup>59</sup> The contribution of genetic material does not create any bond between the donor and the child born,<sup>60</sup> except in the event that a donor participated in a parental project without his knowledge.<sup>61</sup>

Thus, since 2002 assisted procreation has become a real prospect for single women or lesbian couples who want a child without resorting to adoption, while being biologically related to the child<sup>62</sup> and although they do not themselves have a fertility problem.

The filiation of the child born of a parental project formed between two women can be established, first, by the attestation of birth, on which the name of the woman who gave birth will be registered alongside that of her female spouse, on presentation of this attestation of birth to the Directeur de l'état civil (the declaration of civil status is usually made in the hospital following childbirth).<sup>63</sup> In the absence of the declaration by the female spouse of the woman who gave birth, and if these women are married or in a civil union, filiation may be established on the basis of the presumption of filiation set out in Article 538.3 if the C.c.Q.

(civil union) and the whole range of assisted reproduction techniques (sperm, egg and embryo donations). Additional principles were established: the contribution of genetic material cannot in itself serve to create a bond of filiation between the donor and the child; nominative information related to assisted procreation is confidential. The legislator also formally established the nullity of procreation contracts and of surrogacy. See articles 538 to 542 of the C.c.Q., which have now been repealed and replaced by articles 538.2, 538.3, 539, 540 and 541.

- 48 In this respect, the decrease of AID in favour of ICSI tends to indicate that renouncing biological filiation is not so straightforward. (P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.*).
- 49 Pierre NOREAU, "Formes et significations de la vie familiale: des liens entre famille, espace public et le droit", in *Démographie et famille, les impacts sur la société de demain*, Conseil de la famille, Québec, 2001, pp. 45-67; Carmen LAVALLÉE, *Pour une adoption québécoise à la mesure de chaque enfant*, Rapport du groupe de travail sur le régime québécois de l'adoption, March 30 2007, p. 35 [online], <http://www.justice.gouv.qc.ca/francais/publications/rapports/pdf/adoption-rap.pdf>.
- 50 *Ibid.*
- 51 Whether this can be a same-sex couple is not indicated.
- 52 R.S.Q. 2002, c.6 abrogating previous provisions concerning assisted procreation and introducing a new chapter on filiation in the Civil Code: first chapter (art. 538 to 541 of the C.c.Q.).
- 53 Marie PRATTE, "La filiation réinventée: l'enfant menacé?", *Revue générale de droit*, 2003, vol. 33, p. 553 (our translation). This first law in this area was passed in 1980, at which time the legislator established a framework for insemination with donated sperm, the most frequently used technique at the time for infertility (articles 586 and 588 of the C.c.Q [980] prohibiting the disavowal or challenge of paternity where the child was conceived using AID). The legislator took advantage of the reform of the Civil Code (1994) to extend the rule prohibiting the challenge of filiation in the case where a child was conceived using AID, to include unmarried heterosexual couples
- 54 *Ibid.*
- 55 Mireille D. CASTELLI and D. GOUBAU, *Le droit de la famille au Québec*, 5<sup>th</sup> ed., Québec, Presses de l'Université Laval, 2005, p. 229; Jean PINEAU and Marie PRATTE, *La famille*, Montréal, Éditions Thémis, 2006, pp. 678-679.
- 56 Art. 538 of the C.c.Q.
- 57 Art. 541 of the C.c.Q.: "Any agreement whereby a woman undertakes to procreate or carry a child for another person is absolutely null."
- 58 Jean PINEAU and Marie PRATTE, *op.cit.*, p. 678.
- 59 Art. 538.1 of the C.c.Q.
- 60 Art. 538, alinea 1 of the C.c.Q.
- 61 In which case no bond of filiation may be established, in the year following the birth, between the contributor and the child. During that period, where the female spouse of the woman who gave birth to the child is entered on the attestation of birth, her part in filiation must be contested within this period (art. 538.2, alinea 2 of the C.c.Q.).
- 62 In the case of lesbian couples, only one spouse can be biologically related to the child. In some cases, one of the women provides the egg while the other carries the child. They thus develop a special relationship with the child. They may, as a result, "both experience true biological maternity". (Geneviève DELAISI DE PARSEVAL, *Famille à tout prix*, Paris, Seuil, 2008, p. 288). Legally, however, only the woman giving birth will be considered the biological mother of the child.
- 63 Art. 115 of the C.c.Q.: "A declaration of birth states the name assigned to the child, the sex and the place, date and time of birth of the child, the name and domicile of the father, of the mother, and of the witness, and the family relationship between the declarant and the child. Where the parents are of the same sex, they are designated as the mothers or fathers of the child, as the case may be." In addition, see articles 11, 15 and 108 to 114 of the C.c.Q.

On the other hand, the situation is different in the case of a male couple. Indeed, as mentioned above, whereas a sperm donor\* can contribute to the parental project of two women or a single woman, a woman cannot contribute in the same way in the project of two men by entering into a surrogacy agreement with them. Accordingly, the only way for a couple of men to establish a bond of filiation between themselves and a child remains adoption.<sup>64</sup>

In terms of the legal framework for clinical practices of AP, the federal Parliament of Canada passed the *Act respecting assisted human reproduction and related research*<sup>65</sup> in March 2004. This law prohibits a number of practices and establishes the legal framework for activities considered legal. It also creates the Assisted Human Reproduction Agency of Canada (AHRC). Established in 2006, this agency regulates the clinical and research activities of health professionals.<sup>66</sup>

However, in December 2004 the Quebec government referred the constitutionality of this federal law to the Court of Appeal of Quebec on the grounds that it went beyond the legislative competence granted to the Parliament of Canada by the Constitution Act of 1867, and encroached on the power of the provinces to legislate in matters of health.<sup>67</sup> At the same time, in December 2004, the Quebec Minister of Health and Social Services tabled a bill in the National Assembly to regulate AP clinical and research activities;<sup>68</sup> this bill was not adopted and was therefore reinstated on the Order Paper in March 2006. The bill died on the Order Paper following the election of 2007. Since then, two other substantially identical bills were tabled,<sup>69</sup> and finally Bill 26 was introduced in April 2009 and adopted by the National Assembly.<sup>70</sup> The *Act respecting clinical and research activities relating to assisted procreation* received assent on June 19, 2009.

Between the introduction of the Bill in 2007 and its adoption in 2009, the Court of Appeal struck down the provisions referred to it,<sup>71</sup> which temporarily created a legal vacuum. The federal government has appealed to the Supreme Court of Canada, whose decision is awaited, since it will clarify who really has power to legislate in this area. Nevertheless, in the event that the decision of the Court of Appeal of Quebec were dismissed, it would still be possible, under provisions of Article 68 of the federal *Act*, for the Governor in Council to declare that the provisions on regulated activities do not apply in Quebec. For the time being, Quebec law prevails and regulations for implementation should be tabled in the near future.


The elements outlined above highlight the fact that the development of assisted reproductive techniques offered in Quebec is not the only factor explaining the recent surge in AP use; a series of successive factors over several years has also contributed to this surge. It should also be recognized that the more technology diversifies and becomes accessible, the more it spreads. Such is the case, for example, for postmenopausal women who can use an egg donation in order to conceive a child, or for fertile heterosexual couples carrying a hereditary disease who may resort to IVF and preimplantation genetic diagnosis to avoid transmitting the disease to their children. The increased use of AP may also be due to the fact that some women decide to delay having children or they may decide to start a second family at a later age, when their fertility is lower. It should also be noted that male fertility is declining in the general population,<sup>72</sup> while untreated urogenital tract infections<sup>73</sup> have an impact on female and possibly on male fertility, thus increasing the need for assisted procreation treatments.

Moreover, in addition to the many social and legal considerations that help understand the growing interest in these techniques should be noted the difficulties related to the adoption process itself. This process is long and for many people it is discouraging, not to mention that it is also very expensive. In addition, in the case of international adoption, selection criteria for candidates are often rigid and heterosexual couples are generally preferred.

The development of a medical practice that raises questions about such important matters as the social representation of filiation, and the desire to protect people using AP as well as children resulting from AP calls for comprehensive ethical reflection, to guide the actions of stakeholders. The Commission devotes the next chapters to this reflection.

- 64 Art. 546 and 578.1 of the C.c.Q. This state of affairs has been the subject of criticism. See for example Jean PINEAU and Marie PRATTE, *op.cit.*, pp. 682-685 and Alain ROY, “Le nouveau cadre juridique de la procréation assistée en droit québécois ou l’œuvre inachevée d’un législateur trop pressé”, *L’Observatoire de la génétique*, July-August 2005, n° 23, [online], [http://www.ircm.qc.ca/bioethique/obsgenetique/zoom/zoom\\_05/z\\_no23\\_05/z\\_no23\\_05\\_01.html](http://www.ircm.qc.ca/bioethique/obsgenetique/zoom/zoom_05/z_no23_05/z_no23_05_01.html). For a critical analysis of legislative policies regarding filiation, see Marie-France BUREAU, *Le droit de la filiation entre ciel et terre: étude du discours juridique québécois*, Cowansville, Éditions Yvon Blais, 2009 and Anne-Marie SAVARD, “La filiation et la codification au Québec: une approche psychanalytique », *Les Cahiers de droit*, 2005, vol. 46, pp. 411-425.
- 65 *Assisted Human Reproduction Act* (S.C. 2004, ch. 2).
- 66 “AHRC’s mission is to protect and promote the health and safety of donors, patients and offspring born of assisted human reproduction technologies. AHRC does this by administering a comprehensive legislative regulatory framework. [...] It is to foster ethical principles as they relate to assisted human reproduction and other matters that apply” to the act. (HEALTH CANADA, *Healthy Living*, 2004, [online], <http://www.ahrc-pac.gc.ca/doc.php?sid=12&lang=eng>). In this respect, the Agency “monitors compliance with the regulations, manages the licensing framework that regulates acceptable controlled activities in Canada, and enforces prohibitions under the *Assisted Human Reproduction Act*.”
- 67 Order in Council 1177-2004 of December 15 2004 concerning articles 10 to 12 of the *Assisted Human Reproduction Act* and completed in 2006 to widen the reference to the Court of Appeal to include articles 8 to 19, 40 to 53, 60, 61 and 68 (*Gazette Officielle du Québec* of March 8 2006, 138<sup>th</sup> year, Part 2, n° 10, p. 1290). It should be noted that provisions of this same act are incompatible with a number of articles of the Civil Code. For example, it recognizes the validity of surrogacy contracts but prohibits compensation, while acknowledging possible indemnities for the surrogate mother; the act also allows for reimbursement of donors’ expenses and authorizes the Agency to disclose the identity of the donor, with the latter’s written consent, to persons born as a result of these techniques as well as their descendents. See *Human Assisted Reproduction Act, op. cit.*, art. 12 and 18(3).
- 68 Bill 89, *An Act respecting clinical and research activities as regards assisted human reproduction and amending other legislative provisions*, 1<sup>st</sup> Session, 37<sup>th</sup> Legislature, Québec, 2004.
- 69 Bill 23, *An Act respecting clinical and research activities relating to assisted procreation*, 1<sup>st</sup> Session, 38<sup>th</sup> Legislature, 2007, followed by Bill 26, *An Act respecting clinical and research activities relating to assisted procreation*, 1<sup>st</sup> Session, 39<sup>th</sup> Legislature, 2009. Meanwhile, the Commission des affaires sociales has launched consultations on the bill.
- 70 *Journal des Débats*, 39<sup>th</sup> Legislature, 1<sup>st</sup> Session, June 18 2009, vol. 48, pp. 2226-2234
- 71 Reference of the Government of Quebec under terms of the *Court of Appeal Reference Act*, R.S.Q., ch. R-23, relating to the constitutionality of articles 8 to 19, 40 to 53, 60, 61 and 68 of the *Assisted Human Reproduction Act*, S.C. 2004, ch. 2, June 19 2008 : (2008) R.J.Q. 1551(QCCA).
- 72 UNIVERSITY OF EXETER, “Declining male fertility linked to water pollution”, *ScienceDaily*, January 20 2009, [online], <http://www.sciencedaily.com/releases/2009/01/090118200636.htm>.
- 73 Infections of the urogenital tract may affect the bladder and kidneys, but also the vagina, urethra, and cervix. Among these infections may be noted Chlamydia, a sexually transmitted infection. The consequences of these infections for fertility remain hypothetical in the case of men, but have been demonstrated in the case of women: “*C. trachomatis* also causes clinically undetectable salpingitis, which is revealed by tubal sterility. Indeed, severe infection is accompanied by tubal damage, which cause sterility and lead to extra-uterine pregnancy.” (Sophie FOURMAUX and Christiane BEBEAR, “Infections urogénitales liées aux Chlamydia et aux mycoplasmes”, *Progrès en urologie*, 1997, vol. 7, n°1, pp. 132-133) (our translation).





GAMETE AND EMBRYO DONATION:  
BALANCING THE INTERESTS  
OF STAKEHOLDERS

## GAMETE AND EMBRYO DONATION: BALANCING THE INTERESTS OF STAKEHOLDERS

The Commission has focused firstly on clinical practice and its implications for third-party contribution to parental project, in order to better understand the issues and values underlying this participation.

### CLINICAL PRACTICE

When resorting to a third-party contribution to the parental project\*, infertile people must meet a number of requirements which have several similarities. Gamete donors and women receiving donated sperm or eggs must first undergo basic medical examinations in order to assess the health of the persons involved. In addition to medical assessments, psychosocial assessments are also made, and women recipients must complete a consent form<sup>74</sup> that provides important information about the proposed technique.

Before starting any treatment, applicants, whether individuals or couples, are subject to a psychosocial evaluation by a psychologist or psychiatrist.<sup>75</sup> This evaluation focuses mainly on the person's or the couple's understanding of the techniques used and their emotional and psychological comfort with respect to possible consequences.<sup>76</sup> The report of this evaluation is then shared with the medical team; if the team and the professional consulted perceive discomfort about the contribution from a donor, they may revise their decision to pursue AP.

Once the process of fertilization has been completed, people whose parental project involved the contribution of a third party are not required to meet the team of psychologists or social workers again. Moreover, it seems that once their parental project becomes a reality, the vast majority of such people do not contact the fertility clinic again. Those officials consulted at clinics say it is difficult to reach these people to do follow-up on maternal and child health. Despite their gratitude towards the clinic and the donor for helping them realize their parental project, recipients would just as soon forget they used AP services, even though prospective parents are advised at the first meeting with the clinic to let the child know at an early opportunity about its biological origin. Since contact between the clinic and recipients generally ceases once fertilization has been achieved,<sup>77</sup> the experts consulted did not know if children are actually informed about their biological origin in due course.

In the following sections of this position statement, the techniques and practice of insemination with sperm donation, egg donation and embryo donation will be illustrated by means of AP recipient and donor profiles. A complete understanding of all the ins and outs of these practices would have required sketching a portrait of children derived from these techniques. However, given the lack of contacts between fertility clinics and families, very little data on children are available. On the other hand, some studies conducted abroad have focused on the psychological development of children from donated gametes.<sup>78</sup> Some of their findings will be discussed in the section on the ethical implications of gamete donation.

- 74 Procréa Cliniques's *Fertility Treatment Handbook* mentions that, prior to artificial insemination by donor (AID), female recipients must sign a consent form with the physician and/or nurse. Female recipients of eggs must also sign a consent form for anonymous egg donations. These consent forms aim to ensure that female recipients understand the nature of procedures, the lack of any guarantee of success, the medications to be taken and the risks associated with the process.
- 75 Or a social worker for an evaluation of parental aptitude.
- 76 These standards respect the spirit of article 14 of the federal law on assisted reproduction.
- 77 A similar situation prevails in France: "Indeed, CECOS, which delivers gametes, or services performing AP techniques, only see future parents, and generally lose sight of them at the time of conception, or at best, at birth." (P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.*) (our translation).
- 78 On this subject, see A. ORGIBET *et al.*, "Psychopathologie des enfants élevés en milieu homoparental lesbien : revue de la littérature", *Archives de pédiatrie*, February 2008, vol. 15, n°2, pp. 202-210, and Dominique MEHL, *Enfants du don*, Paris, Robert-Laffont, 2008.

## SPERM DONATION

The change in practices surrounding insemination with donor sperm is largely related to the development of semen conservation techniques. Indeed, at room temperature fresh semen can only be conserved for one hour. However, sperm can now be frozen indefinitely in liquid nitrogen using a technique called cryopreservation. This technique has led to the establishment of sperm banks in which samples provided by donors – and by men whose sperm is kept for personal use at a later date – are collected, frozen and stored. They are then given to physicians who perform artificial insemination (AI). AI procedures carried out by infertility treatment programs in hospitals or private clinics are reimbursed by Quebec health insurance; however, the cost associated with semen collection, its treatment,<sup>79</sup> its cryopreservation as well as the number of sperm straws used are generally charged to recipients.

### The technique

Artificial insemination refers to all forms of insemination undertaken without sexual intercourse. There are three main categories of AI, depending on whether sperm is fresh, is supplied by the spouse or is supplied by a donor.

Insemination performed with fresh semen (also called “do it yourself insemination”) is directed mainly at women who wish to become pregnant without having sexual intercourse with the biological father. This form of insemination is performed outside the health system, without either control or medical intervention; it is also called self-insemination.

Insemination using the husband’s or spouse’s sperm (AIH) is conducted in clinical settings.

Insemination using semen from a donor (AID) is a possibility for a woman without a male partner or whose spouse has medical problems, and who prefers not to resort to IVF or in cases where AIH did not result in fertilization or pregnancy. While some clinics are willing to inseminate women with semen from a known donor, most clinics obtain denormalized sperm from sperm banks or from banks under their own management with recruited donors.

Intra-uterine insemination (IUI) is the most common form of non-vaginal insemination. The semen is deposited directly into the uterus using a catheter. IUI increases the chances of fertilization by improving the contact between sperm and egg. In general, the practice of IUI occasions little discomfort and takes about ten minutes.

In Canada, sperm for assisted procreation is considered a drug, and its conservation and use are regulated. A Health Canada Directive entitled *Technical Requirements for Therapeutic Donor Insemination* establishes specific requirements for donor screening and testing for infectious diseases, to which donations must be submitted in order to reduce the potential risk of transmitting infectious agents. In some circumstances, donors who do not meet certain requirements can gain special access to donor sperm, especially in cases where the age of a donor is greater than 40 years, for example.<sup>80</sup>

AI is generally a safe practice. Every 180 days, donor sperm in fertility clinics<sup>81</sup> undergoes several tests for communicable diseases to prevent any contamination of the mother and child from fertilization. In addition, samples are kept for a minimum period of 180 days, so that a second screening test for HIV and hepatitis is performed, and to ensure that the donor was not incubating the virus. The history of donors is also investigated to determine whether they are carriers of a genetic disease.<sup>82</sup> For sperm donors, the risks associated with donation are minimal. In the rare cases where AI may require ovarian stimulation, the risks for women are the same as for any OS.

## The practice

Of the 22 clinics, private physicians' offices and hospitals currently offering AP services in Quebec, 14 practice AID, 9 perform the freezing and storing of sperm, 4 have "small" banks and one runs a donor sperm bank and distributes the banked sperm.

The "small" banks are maintained by institutions affiliated with medical faculties or fertility clinics in hospitals. They usually only meet the needs of patients monitored by the institutions with which these clinics are affiliated. Other banks are under private management. They conserve a larger amount of samples which they sell to physicians performing insemination and from whom they derive profits.

## Recipient profiles

Clinics enable people whose infertility is medically proven to gain access to donated sperm. Heterosexual couples, single women and lesbian couples have access to such donations.

In 2007, according to data obtained by the Commission from one of the clinics consulted, about 50% of donated sperm was used to alleviate a medical indication or unexplained infertility. The remainder of donated sperm went to women who had applied for it on social or personal grounds (about 40% were homosexual women and 10% were single women).

Each year, this same clinic receives 200 to 300 women eligible for insemination with donated sperm. This technique is practiced in women aged 25 to 40 years and the average age of women using it in 2007 was 34 years.

79 Sperm treatment consists in collecting and concentrating it, through the elimination of slow or immature gametes.

80 HEALTH CANADA, *Special Access to Drug and Health Products*, [online], <http://www.hc-sc.gc.ca/dhp-mps/acces/index-eng.php>.

81 Artificial insemination outside of the medical setting poses much greater risks for the transmission of disease.

82 For an overview of Health Canada directives on this subject, see the following website: HEALTH CANADA, "Health Canada Directive: Technical Requirements for Therapeutic Donor Insemination", *Drug and Health Products*, July 2000, [online], [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/prodpharma/semen-sperme\\_directive-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/semen-sperme_directive-eng.pdf).

Sperm donation is also an option for people struggling with infertility after unsuccessful IVF cycles or who lack the financial means to start IVF cycles. Although IVF is a longer process and presents more risks and inconvenience to women (especially where ovarian stimulation<sup>83</sup> and puncture are concerned), many couples consider it preferable to donor insemination since it allows each spouse to provide his or her own genetic contribution. In general, for the child to be biologically related to its father, infertile or subfertile heterosexual couples prefer trying IVF before AID, and this despite the risks associated with IVF for women. On the other hand, IVF is more expensive than AID. One clinic consulted said the choice of insemination with donor sperm may be influenced by monetary factors in some cases. As a result, some heterosexual couples who would have preferred IVF resort to AID because of a lack of sufficient funds.<sup>84</sup>

People resorting to donated sperm must obtain a satisfactory psychological evaluation. The specialist meeting them discusses general issues and asks more pointed questions related to the male spouse's feelings about the decision to use donated sperm. The specialist then seeks to understand how the male spouse perceives himself, and how he will perceive himself as father of the child resulting from fertilization. The clinics consulted mention that a minority of people requesting AID do not meet psychological evaluation criteria.

Finally, the team will note on a matching form the physical characteristics of applicants and the region where the woman was born to avoid the risk of consanguinity. From these data, the team performs systematic matching, to select a donor based on the compatibility of its physical characteristics with those of recipients. Overall, the team seeks a donor who physically resembles the social father, in terms of eye and hair colour, blood type, height and weight. This same information about the donor is transmitted to recipients.<sup>85</sup> On request, some clinics also agree to disclose the religion and education level of the donor. The clinics consulted note the great importance attributed by heterosexual couples to the physical resemblance of the donor and the child's father.

Once insemination results in the birth of a child, and if recipients wish to use sperm from the same donor at a later date to maximize the chances of likenesses between siblings,<sup>86</sup> they can come to the clinic and buy additional sperm straws derived from donations from this man (provided such straws or the donor himself are still available). A long-term freezing file is opened for these persons and annual storage fees are charged. A consent form specifically designed for this purpose provides that sperm straws so purchased become the property of the persons concerned and will not be refunded if the straws are not used.

### Donor profiles

Potential donors must be between 18 and 40 years of age, have a stable sexual life (with only one sexual partner during the previous six months), be in good physical and mental health, and know the identity of their biological parents so their medical history can be determined. One fertility clinic consulted attributes the participation of voluntary donors to some posting of notices on university campuses, to the reimbursement of travel expenses and especially to word of mouth. One of the sperm banks consulted receives between one and two potential donors a week.

Potential donors are first met by a reproductive health counselling professional, who assesses underlying motivations, characteristics and expectations of the donor. Potential recipients need and generally get a positive psychological evaluation in order to proceed with insemination. But the situation is different for potential donors who are turned down in 30% of cases, whether because of their motivation, psychological state or general appearance. In addition, potential donors expressing a desire to develop a bond with the child, those with unusual expectations and those with "non-standard" physical features are not accepted.

The motivation most often expressed by potential donors is their wish to help people who cannot procreate naturally. The consent form presented to potential donors includes the requirement to undergo many medical tests, screening for known genetic mutations responsible for cystic fibrosis\* and karyotype\* screening. The potential donor must record his wish whether to know or not to know the results of genetic tests. He is also made aware that he must undergo a blood test every six months following his last donation. Regarding the anonymity of his donation, he is informed that he will not receive any information enabling him to identify the couple or person receiving the donation. The form states finally that all information relating to sperm donation is in principle confidential. However, if the donor expressly gives his consent, information that can be used to identify him may be disclosed to those persons concerned, on request.<sup>87</sup>

The potential donor is notified that his donation will be used to inseminate one woman or several women who wish to become pregnant, or in the *in vitro* creation of embryos for the parental project of a person or couple. The form states that it is possible the number of embryos obtained by IVF from the donation will exceed the reproductive needs of the person for whom they are intended and this latter person may, in such an event, consent to the use of spare embryos\* for research purposes.<sup>88</sup> However, no clause in the consent form states explicitly that the donation may be destined for persons with medical indications of infertility as well as for single women or homosexual couples.<sup>89</sup>

Potential donors meeting all biological and psychological requirements evaluated during the four stages of selection (approximately one donor out of ten is accepted) must observe a period of sexual abstinence for about three days. Subsequently, donors will travel to the clinic, on average twice a week, to make their donation. In the case of donors turned down, it seems that many of them experienced disappointment about being excluded from the sperm bank, and some of them learned about their own infertility at that time.

Although the donor is not paid, his travel expenses are generally reimbursed with or without receipts up to a limit of \$50 per donation and up to a maximum of \$2,000. One clinic consulted withholds such repayments until the final audit is carried out, six months after the last donation.

Once the donor is chosen by the sperm bank program, all donations will be allocated exclusively to parental projects. Sperm straws are quarantined for a minimum period of six months. After this observation period, samples are subjected to further tests and the donor's file is updated before semen is made available.

- 83 Ovarian stimulation and ovulation induction drugs can also be used with AID.
- 84 An *in vitro* fertilization costs around \$10,000 whereas an insemination cycle using donated sperm costs less than \$1,000.
- 85 This information respects the spirit of article 15(4) of the federal *Human Assisted Reproduction Act* concerning the disclosure of health reporting information which includes personal characteristics (art. 3).
- 86 Victoria M. GRACE, Ken R. DANIELS and Wayne GILLET, "The donor, the father, and the imaginary constitution of the family: Parent's constructions in the case of donor insemination", *Social Science & Medicine*, 2008, vol. 66, n°2, p. 310.
- 87 Which respects the spirit of articles 15(1) and 15(4) of the federal *Human Assisted Reproduction Act*.
- 88 The present position statement focuses on analysing issues related to gamete donation for reproductive purposes and does not raise gamete donation for research purposes.
- 89 This information is also required under regulations in article 8 of the federal *Human Assisted Reproduction Act* which, it should be remembered, has been declared unconstitutional by the Court of Appeal of Quebec.

Donations from the same donor will be collected and used until 25 children are born per million population (more births from the same genetic background could lead to risks of consanguinity in the population). If the figure of 25 births is reached, then the clinic informs the donor that he cannot donate further. However, at present, no action is taken to ensure that he will not continue to donate at another clinic in the same region. Likewise, no attempt is made at the beginning of the program to determine whether this same individual has already made past donations at other clinics in the same region.

### Outcomes

In Quebec, a single clinic was consulted which runs a sperm bank and distributes sperm through fertility clinics in the province. This clinic estimated that over the last ten years, 1,600 children were born as a result of donated sperm. The vast majority of these donations were used in artificial insemination programs (98%) rather than in IVF programs (only 2%). The clinics consulted indicate that ART using sperm donation obtain substantially the same outcomes as conjugal insemination programs.

The Canadian Assisted Reproduction Technologies Register does not record the results of insemination. In France, the outcomes published by the Agence de la biomédecine for 2006 indicate that about 11% of insemination cycles (with the spouse's sperm or that of a donor) led to childbirth<sup>90</sup> (this figure does not indicate whether the birth occurred at term).

## EGG DONATION

### The technique

Egg donation is usually offered to women who lack ovaries, suffer from ovarian failure, have experienced early menopause or are too old to procreate naturally.<sup>91</sup> Fertilization of a spouse's sperm<sup>92</sup> and a donated egg must take place *in vitro*. Egg donation requires a greater time commitment from the donor than sperm donation. Indeed, the egg donor adheres to part of the IVF protocol, namely by taking medication to regulate and stimulate the production of ova before their removal.

This hormone therapy has two objectives: to stimulate the ovaries to produce several mature eggs and to prevent premature ovulation before sampling. Various drugs<sup>93</sup> and strategies may be used for this purpose. The treatment plan and the choice of drugs will be based on test results and the personal history of the two people providing the gametes used for fertilization (the male partner in the case of the applicant couple and the donor). In addition, drugs will have to be used to coordinate and synchronize the treatment cycles of the two women (the donor and recipient) so that the recipient's uterus is ready to receive the embryos in the days after fertilization.

## Egg retrieval<sup>94</sup>

Women receiving hormone therapy are closely monitored, using vaginal ultrasound and measurement of serum estradiol (analysis of hormone levels in the blood) before egg retrieval. Ultrasounds are performed at the start of ovarian stimulation and, subsequently, at a frequency of one to two days apart, once follicle growth has been established. Gonadotropin\* dosage is adjusted depending on results of ultrasound and blood analysis. Interruption of a treatment cycle may be considered if there is inadequate response to hormone therapy or if ultrasound reveals an excessive response to medication and a high risk of OHSS.<sup>95</sup>

The monitoring continues until at least three follicles reach maturity. Egg retrieval is then planned. Final follicular maturation is induced by administering an injection of human chorionic gonadotropin (hCG) 35 hours before retrieval.

Retrieval takes approximately 20 to 30 minutes, but can vary depending on the number of follicles. The discomfort of the intervention is minimized by administering an analgesic in the vagina and a powerful intravenous sedative and analgesics at regular intervals. At the request of donors, retrieval can be performed under spinal or general anesthesia.

The period during which retrieval can take place lasts from one to two hours, or until the effects of anesthesia have worn off. Bleeding can occur but is rarely abundant. The donor may also experience discomfort in the form of cramps, which can be relieved by taking antihistamines.

## *In vitro* maturation

The value of *in vitro* maturation (IVM) is that it does not require hormone therapy, unlike IVF. The immature eggs are retrieved from the donor and brought to maturity in the laboratory over a period of 24 to 48 hours. The mature eggs are fertilized and transferred into the uterus of the recipient as in the case of IVF. Donors under 38 years of age, whose ovaries contain several follicles and who are at risk of developing OHSS or who have already suffered from this syndrome,<sup>96</sup> may be candidates for IVM.

IVM is also available to women who need egg donations and wish to avoid the disadvantages, costs and risks that come with egg donation and also with gonadotrophin treatment associated with OS of the donor. However, IVM is generally less effective than IVF with OS, because some women do not produce enough follicles naturally.<sup>97</sup> IVM may seem more “natural” than IVF, but the eggs remain longer in a Petri dish<sup>98</sup> than during IVF. It should be noted that drugs are generally administered to the recipient to facilitate embryo implantation. Considering the small number of children born as a result of this procedure as well as the lack of monitoring of these children, this practice is considered experimental.

- 90 AGENCE DE LA BIOMÉDECINE, *Rapport annuel - Bilan des activités de l'Agence de biomédecine 2007*, p. 52. Moreover, singleton deliveries accounted for about 86% of deliveries following artificial insemination by donor. (AGENCE DE LA BIOMÉDECINE, *Bilan des activités de procréation et de génétique humaine en France 2006, 2007*, [online], [http://www.agence-biomedecine.fr/fr/rapport\\_2007/assist/2\\_amp\\_sperma/2\\_1/2\\_tabetfig.htm](http://www.agence-biomedecine.fr/fr/rapport_2007/assist/2_amp_sperma/2_1/2_tabetfig.htm)).
- 91 In 2005, 301 IVF + ICSI cycles and 110 cases of frozen transfer of embryos derived from donor eggs involved egg donation. In addition, the average age of women in Canada in 2005 resorting to egg donation was 41 years, compared to 35 years for IVF + ICSI and frozen embryo transfer. (Joanne GUNBY *et al.*, *op. cit.*).
- 92 The sperm and egg are sometimes both donated, although this situation is quite rare.
- 93 IVF requires significant medication, as described in the appendices.
- 94 MCGILL REPRODUCTIVE CENTRE, *In vitro fertilization*, [online], <http://www.mcgillivf.com/e/McGillIVF.asp?page=184.186.210#Medication>.
- 95 Studies have shown that a type of polymorphism in the receptor gene of the follicle-stimulating hormone (FSH) would seem to have greater resistance to the action of this hormone. The outcomes could make it possible to determine the needed dose of hormone to be administered to each woman in order to obtain an adequate response and also to avoid complications associated with ovarian hyperstimulation syndrome. (D. LOUTRADIS *et al.*, “Pharmacogenetics in ovarian stimulation – current concepts”, *Annals of the New York Academy of Sciences*, 2008, vol. 1127, n°1, p. 10).
- 96 MCGILL REPRODUCTIVE CENTRE, *In vitro maturation*, *op. cit.*
- 97 IVM costs approximately \$2,000 less than IVF. According to data obtained in 2002, the clinical pregnancy rate using IVM is 23 %, compared to 36 % for IVF. On average, 10 oocytes are retrieved from women who have undergone IVM compared with 15 from women who have undergone IVF. (Tim J. CHILD *et al.*, “A comparison of in vitro maturation and in vitro fertilization for women with polycystic ovaries”, *Obstetrics & Gynecology*, October 2002, vol. 100, n°4, p. 668).
- 98 A Petri dish is a flattened cylindrical dish for the culture of micro-organisms or of cells.

## Embryo transfer

Embryo transfer takes place from two to five days after egg retrieval, and sometimes later again, in order to choose the best embryos. The decision as to the timing of the transfer is based on the number and quality of embryos. With respect to the number of embryos transferred, the decision depends on the age of the woman, on her previous pregnancies, on the results of previous treatments and on the quality of embryos.<sup>99</sup> Before beginning treatment and at the time of transfer, each person involved receives information regarding the possible effect of the number of embryos implanted on the risks of multiple pregnancy and the likelihood of successful implantation. At the time of their transfer, the embryos are encased in a thin plastic catheter and inserted into the uterine cavity. This procedure takes about 15 minutes and is usually not painful. Once the embryo transfer has been completed, the recipient may take continue her usual activities as before.

## Risks associated with treatment<sup>100</sup>

For recipients, the main risk associated with IVF, as with AP in general, is that of multiple pregnancy. The risks of disease transmission are generally low, since the donor must undergo several medical tests before being selected for the donation. However, unlike sperm donation, egg donation only requires the donor to take a single HIV and hepatitis test, whether the donation is directed or paired. As a result, in cases where the donor may recently have been infected, the virus is not detectable serologically.

For donors, OHSS is a relatively rare risk (1.6%),<sup>101</sup> although a worrisome one. Several degrees of severity of this syndrome exist.

Retrieval as such is associated with only a very low risk of complications, although it may be associated with pelvic infection in one out of 500 and with severe bleeding in one case out of 1000.<sup>102</sup> Light bleeding is benign, but more serious bleeding of the vaginal wall may require arterial ligation. Very rarely, the bowel wall may have been affected during puncture, requiring a prescription of antibiotics.<sup>103</sup>

## Egg donation programs

There are four types of egg donation worldwide, namely anonymous donation, directed donation, paired or direct donation and shared donation.

In Quebec, the first three of these types of donation are available. The terms recruitment of donors varies from one program to another. Of the 22 private clinics and hospitals offering AP services in Quebec, five offer an egg donation program. Three of them seek to recruit anonymous donors, but since volunteers rarely come forward, these programs also offer applicants the choice of finding their own donor, whether in their communities, through classified ads or even on the Internet. This type of program is called “directed donation”; applicants recruit a donor who must consent to the donation and meet the program teams before providing her eggs to the woman needing them. The donation is not anonymous. It is even possible for the donor to follow the evolution of pregnancy and development of the child (for example, if she is a member of the family).

Two clinics offer a program of “paired donations,” in order to preserve the anonymity of donors. Once again, applicants are the ones seeking out the donor. However, the donor recruited in this manner is not the one providing them with eggs. Actually, the donor is code-matched with a single person or couple who also await a donation, and who have already recruited a donor who meets all inclusion criteria. The paired donation program seems equitable and respectful of confidentiality, but the teams performing paired donation see a problem with it: when a donor recruited by couple or woman “X” provides many healthy eggs that allow fertilization of an embryo destined for couple or woman “Y”, whereas the latter paid for treatment which did not lead to retrieval, then couple or woman “X” may feel wronged and may lodge a complaint with the clinic. Although this couple or single woman may have recruited and paid the costs for treatment of a donor, enabling another couple or single person to fulfill the parental project, but does not have access to an egg.

Shared donation (or egg sharing) is a donation program used in Great Britain since 1992. In this case, a woman who wishes to start a stimulation procedure for IVF may be asked to share her eggs with another woman in exchange for lower costs of her own treatment. The needs of these two women are then fulfilled by the exchange of a lower cost for one woman and the opportunity to benefit from unused eggs for the other.<sup>104</sup>

## The practice

### Recipient profiles

In general, women who use donated eggs do so because of their age (egg production decreases with age), because they experience early menopause or because they have suffered several *in vitro* fertilization setbacks with the use of their own eggs.

Women to whom egg donation is proposed are generally between 26 and 51 years old.<sup>105</sup> A clinic consulted excludes women over 50 years of age, since the response to treatment decreases significantly with age. The average age of women who received donated eggs is 41 years while the average age of menopause is 53 years. Age is not the only criterion for exclusion – general health is also important. More and more Canadian clinics refuse to treat women who are too old or who have a body mass index exceeding 32 kg/m<sup>2</sup>,<sup>106</sup> although the Society of Obstetricians and Gynecologists of Canada (SOGC) has not yet issued guidelines in this area.

- 99 According to 2005 data from the Canadian register, the number of embryos transferred varies between one and thirteen, with an average of 2.4 embryos per IVF cycle. A single embryo was transferred in 11% of cases, two embryos in 57% of cases and three embryos in 23% of cases. Women having received four or more embryos during a single transfer had an average age of 39, compared to 37 for women having received three embryos and 34 for those having received two embryos. The data show a significantly increased rate of pregnancy when two embryos are implanted rather than one (41.8% compared to 20.1%), whereas implanting more than two embryos does not result in an increased pregnancy rate. (Joanne GUNBY *et al.*, *op. cit.*).
- 100 As in the case of sperm donation, different risks related to techniques and to the experience of the person undergoing the fertilization process are described on the Health Canada website. (HEALTH CANADA, “Consultation Background Paper, Conduct of Controlled Activities under the *Assisted Human Reproduction Act*”, *Healthy Living*, [online], <http://www.hc-sc.gc.ca/hl-vs/pubs/reprod/2007-conduct-execution/index-eng.php>).
- 101 According to 2005 data from the Canadian register, there were 111 cases of ovarian hyperstimulation, 45 of which required hospitalization, 17 complications related to medications administered (without hospitalization) and seven complications related to procedures, including six hospitalizations. (Joanne GUNBY *et al.*, *op. cit.*).
- 102 *Ibid.*
- 103 Franz FISCHL and Johannes HUBER, “Traitement moderne de la stérilité”, *Forum Medical Suisse*, 9 April 2003, n°15, p. 366, [online], [http://www.medicalforum.ch/pdf/pdf\\_f/2003/2003-15/2003-15-558.PDF](http://www.medicalforum.ch/pdf/pdf_f/2003/2003-15/2003-15-558.PDF).
- 104 THE LONDON WOMEN'S CLINIC, “Ova”, *The Magazine of the London Women's Clinic*, 2008, p. 6 and HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA), *Code of practice*, 8<sup>th</sup> ed., 2009, s.12.
- 105 According to 2005 data (Joanne GUNBY *et al.*, *op. cit.*).
- 106 “Epidemiological data clearly show that being overweight contributes to an increased frequency of cycle disorders and infertility but also of more frequent miscarriages and morbid complications during pregnancy. Treating obesity before conception is an important step in that it contributes to improved outcomes with lower medical risk and lower cost.” (P. LEFEBVRE and J. BRINGER, *Obésité et reproduction*, [online], <http://www.gyneweb.fr/Sources/fertilite/obesite.htm>) (our translation).

Like sperm donation programs, egg donation programs require that applicants meet with a psychologist or psychiatrist specializing in infertility or reproductive health. The meeting deals with general aspects similar to those discussed in the case of sperm donation, and also focuses on the woman's feelings. Indeed, the woman who must resort to donated eggs has to mourn her own infertility, her inability to bring a child into the world who is biologically related to her. The professional seeks to ensure that she accepts the situation and is willing to run the risks of IVF.

In general, women who are willing to undergo IVF treatment using donor eggs and all related steps attach great importance to the genetic bond established through the sperm of their spouse, the biological father of the child to be born. The psychologist raises this issue and confirms whether the woman is personally motivated to proceed with egg donation or whether she is under family or spousal pressure to comply. Generally, most women meet evaluation criteria.

The psychological evaluation meeting also aims to explore the woman's vision of herself and how she is perceived by those around her. The woman who intends to participate in an egg donation program may have doubts about her own identity as mother, after discovering her own infertility and then realizing the child will be conceived with another woman.

Heterosexual couples seem especially concerned about the sperm donor's physical characteristics (size, hair and eye colour), but in the case of egg donation, they are more concerned about the egg donor's\* personal characteristics (habits, allergies, education, even if such information is not necessarily disclosed). Several hypotheses could account for this phenomenon. For example, the selection of sperm donors on the basis of physical criteria enables heterosexual couples, and particularly the father, to appropriate the child and to avoid doubts about his biological paternity. Men might "need" the child to resemble them, so their relatives recognize them as the father. For their part, because women carry and give birth to the child, they seem less concerned with the donor's physical appearance.

Physicians, nurses and psychologists who meet people awaiting donation make sure that they understand the risks associated with the procedure and that they give their free and informed consent. The consent form informs them of these risks and mentions the possibility that no egg may be recovered during retrieval. These applicants must also choose whether the collected eggs will be fertilized with the spouse's sperm or with that of a donor. Again, the form states that there is no certainty about the outcome of fertilization.

If fertilization is successful, then recipients are informed that two or three embryos will be transplanted into the uterus of the woman and that this transfer is associated with risks of multiple pregnancy. However, the form does not specify how many embryos will be transferred or how or by whom the decision will be taken. Where the fertilized embryos are concerned, the form indicates that in the event of a surplus, the couple or single woman must choose whether to keep supernumerary embryos for future use, to destroy them or to donate them to the clinic for research purposes. Recipients are informed that in the event of separation and divorce, only the person owning the reproductive material used for embryo fertilization will make choices about supernumerary embryos.<sup>107</sup>

In egg donation programs, the form states that no information identifying the donor will be sent to recipients, except in cases where the donor has expressly consented that such information be disclosed. Single applicants or applicant couples are informed of their obligation to pay all costs related to treatment administered to the donor, to her appointments with the psychologist and to any travelling involved. In the case of a paired or a directed donation, one of the clinics consulted used a form stating that it is “strongly recommended to conclude a written agreement about the donation with the egg donor recruited, separately from this consent form, in order to indicate [their] respective obligations.” The signature of such “agreements” is however performed outside the clinic and the managers of egg donation programs do not examine the terms of such agreements.<sup>108</sup> Finally, as in the case of sperm donation, recipients of egg donation sign a form in which they pledge to report in writing to the clinic any pregnancies resulting from donation, as well as the birth of one child or more, as the case may be, including the child’s health state, sex and date of birth.

When meeting with the medical team, the couple or single person verbally explains its expectations regarding the program and selection of the egg donor. Teams respect selection criteria for donors, since they are ready to meet these expectations. In general, people who have previously recruited a donor for another couple or single person (paired donation), obtain a transfer of embryos within six to nine months. However, for those requiring a healthy woman who presents matching characteristics (eye and hair colour, height, weight and blood type), the current waiting time is approximately nine to twelve months. Finally, the requests of people for more specific criteria (education, career, skills, etc.) are noted, but these people are warned that they will have to wait longer for such a donor to be recruited.

### Donor profiles

The vast majority of egg donors are recruited by applicants.<sup>109</sup> Egg donors must be between 18 and 35 years of age, exhibit no exclusion criteria,<sup>110</sup> be in good health and have a primarily altruistic motivation. A psychologist<sup>111</sup> meeting a potential egg donor seeks to understand the woman’s underlying motivations, her understanding of risk and her feelings about the fact that she will never be the social mother of the unborn child.

107 In the spirit of the federal *Assisted Human Reproduction Act* and regulations concerning article 8.

108 See article 7 of the federal *Assisted Human Reproduction Act*, which, it should be remembered, has been declared unconstitutional by the Court of Appeal of Quebec.

109 For the year 2007, in four clinics consulted, five donors came forward to donate eggs of their own accord.

110 See the complete list of exclusion criteria in the appendices.

111 In several clinics consulted, instead of meeting a psychologist, the donor meets a nurse responsible for the egg donation program.

The psychologist also discusses the consequences of directed donation to discover the feelings of the donor about the fact she may know the child resulting from this procedure. The psychologist examines whether she is making the donation under any social or family pressure, inquires about the degree of autonomy in this decision, and looks for any reluctance in people who are vulnerable economically or emotionally. This meeting is presented as a necessary step for donors but, according to one clinic consulted, physicians rarely propose that donors bring along their spouse (if they have one). The spouse of the egg donor is not required to consent to donation, or to visit the clinic. Generally, once physical tests and the psychological evaluation have been performed, the majority of donors recruited by people awaiting donation are accepted as such.

One Quebec clinic provides the donor with a questionnaire designed to respond to requests about her personal characteristics. She should also mention her religion<sup>112</sup> and that of her father and mother. The donor is also asked to state how often she takes part in physical activities, and to describe her “psychological history.”<sup>113</sup> In a section of the questionnaire devoted to “medical history,” the donor must for example indicate her height, the eye and hair colour of her father, mother, each of her children, her brothers and sisters and her maternal and paternal grandparents. She must also indicate her consumption of cigarettes (and if she has stopped, she must indicate when she did so), her consumption of drugs and alcohol, whether she has already had “legal problems” in the past, whether she has already been convicted of a crime, whether she has “served time in prison.” Finally, she must respond to an exhaustive list of questions about her academic and professional development, and describe her talents, interests and hobbies, as well as her personality and her ultimate goal in life.

## EMBRYO DONATION

In Canada, embryo donation is a very rare practice. Only one clinic has an embryo donation program.<sup>114</sup> In 2005, 33 frozen embryo transfers resulting from embryo donation were performed.<sup>115</sup> In Quebec, embryo donation does not yet exist, but at least one clinic plans to create such a program.

In France, the practice of embryo donation is legally permitted and has been regulated since 1999.<sup>116</sup> According to the Maia website, very few people chose to donate their embryos, with the result that it remains a marginal practice. Also, given that there are more applicants than donors, the waiting time for embryo donation is between one and two years.<sup>117</sup>

Once people are fully engaged in the process of procreation, they are generally reluctant to donate their embryos. They prefer to keep a bank of frozen embryos, destroying them or providing them for research purposes once they have completed their project of having a child. In addition, many couples find it emotionally difficult to decide the fate of supernumerary embryos.<sup>118</sup>

According to one Quebec clinic consulted, when respondents are asked early on in the AP process whether they would like to donate surplus embryos, they are generally reluctant to do so. However, once their project of having a child is fulfilled, it would seem they are more willing to do so.

An Australian study has brought to light another phenomenon: initially, couples are ready to help other couples in the same situation, but once the project of having a child is completed, they feel they are donating a child and not just an embryo.<sup>119</sup> People's attitudes differ depending on whether the embryos were formed from their own gametes or from donated gametes.<sup>120</sup> People who preferred to destroy excess embryos said they did so out of a desire to cut the emotional bond with the embryos. Thus, for such people, as long as the embryos exist, the emotional bond also continues to exist.<sup>121</sup> Some people would be more willing to donate their embryos if they had information on potential recipients, so they had some way of making sure that children resulting from their donations were raised in a loving, stable environment. Conversely, others would be willing to donate their embryos if they could be sure of complete anonymity.<sup>122</sup>

Two of the three Quebec clinics consulted report that, despite the parents' consent to destroy embryos, and even when fees have not been paid to freeze embryos, clinics are reluctant to destroy them, whereas in some countries such as the United Kingdom, the law provides for a maximum waiting time of 10 years.<sup>123</sup>

Nonetheless, until recently, the transfer of embryos frozen by vitrification has given poorer results than the transfer of fresh embryos.<sup>124</sup> However, with improved freezing techniques, embryos (and gametes) can now be preserved for ever-longer periods, without compromising embryo quality or the safety of their transfer;<sup>125</sup> research is nonetheless being undertaken in this area. Unlike the slow freezing technique, it would seem that vitrified embryos are much likelier to survive.<sup>126</sup> However, given that the technique of vitrification is relatively recent, few frozen embryos could be used. Moreover, the unpopularity of this practice worldwide makes it difficult to establish comparisons and statistics.

- 112 This question is important for several faiths which consider that religion is transmitted by the mother.
- 113 Among other things, if she has already received treatment for depression or emotional problems, or if she has taken antidepressants for more than three months.
- 114 MOUNT SINAI, *Donor embryo recipient program*, [online], [http://www.mtsinai.on.ca/Reproductivebiology/\\_private/Programs/donorembryorec.htm](http://www.mtsinai.on.ca/Reproductivebiology/_private/Programs/donorembryorec.htm).
- 115 Joanne GUNBY *et al.*, *op. cit.*
- 116 Code de la santé publique (Code of Public Health), articles L.2141-4 to 2141-6
- 117 Maia is an association helping people who experience infertility (<http://www.maia-asso.org/don-embryon.html>).
- 118 Giuliana FUSCALDO, Sarah RUSSELL and Lynn GILLAM, "How to facilitate decisions about surplus embryos: patients' views", *Human Reproduction*, 2007, vol. 22, n°12, p. 3130.
- 119 Sheryl DE LACEY, "Parent identity and 'virtual' children: why patients discard rather than donate unused embryos", *Human Reproduction*, 2005, vol. 20, n°6, pp. 1663 and 1666-1667.
- 120 Giuliana FUSCALDO, Sarah RUSSELL and Lynn GILLAM, *op. cit.*, p. 3130.
- 121 *Ibid.*, p. 3133.
- 122 *Ibid.*, pp. 3134-3135.
- 123 *Human Fertilisation and Embryology Act, 1990*, article 14 (4A), introduced in 2008 during revision of the law (*Human Embryology Act, 2008*, Ch.22, art. 15)
- 124 While the implantation rate is about 20% with slow freezing, the rate climbs to 40% with freezing by vitrification and to 52% with fresh embryos. (S.E. ELIZUR *et al.*, "Cryopreservation of oocytes in a young woman with severe and symptomatic endometriosis: A new indication for fertility preservation", *Fertility and Sterility*, January 2009, vol. 91, n°1, pp. 293.e1-293.e3). Furthermore, with slow freezing, high-quality embryos are needed, while vitrification makes it possible to use embryos of lesser quality
- 125 According to a 2004 study: "Interestingly, evidence suggests that human embryos can be safely cryopreserved and successfully thawed following up to 12 years (and possibly longer) of frozen storage." (A. REVEL, "Twin delivery following 12 years of human embryo cryopreservation: case report", *Human Reproduction*, 2004, vol. 19, pp. 328-329, cited by Giuliana FUSCALDO, "Spare embryos: 3 000 reasons to rethink the significance of genetic relatedness", *Reproductive BioMedicine Online*, 2005, vol. 10, n°2, p. 165).
- 126 80-85 % following vitrification, compared to 50-65 % following slow freezing. See Ri-Cheng CHIAN *et al.*, *op. cit.*

## THE VALUES AT STAKE

For the Commission, gamete and embryo donation challenges the key values of the welfare of the child, the dignity of the human person, equality, reproductive autonomy and privacy.

The well-being of children is the responsibility of all actors and implies that the child resulting from AP faces the same opportunities as naturally conceived children, in terms of physical and psychological development.

The value of human dignity is contained in the principle that the human person itself should be considered as an end and not as a means to an end. This value excludes all forms of instrumentalization, reification\* and commercialization of the human body, its tissues, organs and products. The human body and its products (organs, gametes, uterus) cannot be sold or rented, as this would involve their entering into a commercial transaction, which violates the very foundation of human dignity:

« [T]he mercantile disintegration of individual bodies will have a dissociative effect on the social body, because it destroys fundamental symbols and community feelings: basic solidarity, the social bond, altruism and generosity, the way the bodies of others is perceived and therefore the relationship with the other person... No human society can tolerate such a dismemberment of its members The symbolism of the donation as pure, disinterested relation is therefore socially necessary.<sup>127</sup>



However, out of solidarity or altruism, a person may decide to donate part of its body or body products to another person. Thus, parents may feel privileged by their family situation and may wish to donate gametes or embryos in order to enable others to fulfill the same wish for children, which is a completely legitimate motivation; in the eyes of the law, the donation acquires its legitimacy from this motivation.

In terms of equality, the Commission has noted the disparities caused by Quebec legislation between gay and lesbian couples, men and women and between women.<sup>128</sup> Among other things, the law creates two categories of mothers and of children. On the one hand, female lesbian couples can resort to artificial insemination with donated sperm, whereas co-parenting, which would allow a gay couple to have a child with a pair of homosexual women, is prohibited under Quebec law. On the other hand, a single woman can undertake a parental project through recourse to donated sperm, whereas the male equivalent is not possible because a single man would need recourse to a surrogate mother, something which is prohibited under Quebec law. Furthermore, by allowing a homosexual woman to become a mother without giving birth, the law creates a disparity between lesbian women and heterosexual women. In fact, when heterosexual women cannot bear children, they cannot aspire to become mothers, since a mother is the female person giving birth to the child. In addition to these disparities, the Civil Code draws a distinction between adopted children and children resulting from donated gametes (very rarely from donated embryos): adopted children are able to access information about their biological parents starting at the age of 14 years, whereas children resulting from donated gametes are not allowed to access such information.

Reproductive autonomy may be defined as the ability of a person or couple to decide independently whether or not to reproduce, and to choose the means to do so. Paradoxically, reproductive autonomy may imply that a couple or person will need a third person or a medical technology to achieve its parental project. While Quebec society recognizes the values of freedom of choice and autonomy, these values must also be reconciled with other values such as human dignity, welfare and the health of women and children. To this end, the exercise of reproductive autonomy is subject to constraints imposed by the legislature and the medical profession: “autonomy is not an absolute right and may be limited in the legislation if such limits agree with the principles of fundamental justice and are justifiable.”<sup>129</sup>

Respect for privacy can be defined as the right to control information concerning us and to protect this information:<sup>130</sup>

« Privacy includes a right to be free from intrusion and interruption. It is linked with other fundamental rights such as freedom and personal autonomy. In relation to information, privacy involves the right of people to determine when, how and to what extent they share information about themselves with others.<sup>131</sup>



As a result, this concept implies the freedom for individuals to keep certain information about themselves confidential. However, respect for one’s identity, as a component of the right to privacy, includes the right of the child to have access to its origins. The concepts of dignity, freedom, integrity and equality are also invoked in this sense. It is on this basis that anonymity has been lifted in many countries.<sup>132</sup>

- 127 Gilbert HOTTOIS, “Corps humain”, in Gilbert HOTTOIS and Jean-Noël MISSA (eds.), *Nouvelle encyclopédie de bioéthique*, Brussels, DeBoeck Université, 2001, p. 248 (our translation).
- 128 Marie-Blanche TAHON, “Nouvelles formes de régulation de la famille au Canada et au Québec: avant-gardisme et marginalisation”, *Enfances, Familles, Générations*, Autumn 2006, n°5, [online], <http://www.erudit.org/revue/EFG/2006/vn5/015779ar.html>.
- 129 Julie COUSINEAU, “L’autonomie reproductive: un enjeu éthique et légal pour le diagnostic préimplantatoire”, *Revue du Barreau canadien*, 2008, vol. 86, p. 471 (our translation).
- 130 Sonya AUDY, *Le respect de la vie privée et la protection de la confidentialité en recherche*, document drafted for the Comité de liaison en éthique de la recherche de l’Université de Montréal (CLÉRUM), 14 March 2006, pp. 3-4, [online], <http://www.recherche.umontreal.ca/PDF/Vie%20privee-Confidentialite.pdf>.
- 131 CANADIAN INSTITUTES OF HEALTH RESEARCH (CIHR), *CIHR Best Practices for Protecting Privacy in Health Research*, 2005, p. 111, [online], <http://www.cihr-irsc.gc.ca/e/29072.html>.
- 132 Michelle GIROUX, “Le droit fondamental de connaître ses origines biologiques”, in *Droits de l’enfant, Actes de la conférence internationale*, held in Ottawa in 2007, Montréal, Wilson et Lafleur, 2008, pp. 355-373; Irène THÉRY, “L’anonymat des dons d’engendrement est-il vraiment éthique?”, *Esprit*, 2009, n° 354, p. 133; Geneviève DELAISI DE PARSEVAL, “Comment entendre la levée du secret des origines”, *Esprit*, 2009, n° 354, p. 165.

## ETHICAL ISSUES

The third-party contribution to the parental project, through gamete or embryo donation, raises issues of two kinds. The first concerns the development of the child resulting from such a donation. This issue concerns the influence of the genetic bond in relation to the social bond, as well as the child's access to its origins, in conjunction with respect for the privacy of its parents and the right of donors to remain anonymous. The second issue concerns the concept of the dignity of the human person, the commercialization of the human body and its products, and the instrumentalization of human beings. The question of instrumentalization implicitly involves the right of infertile people to fulfill their desire for children.

### The development of children resulting from a donation

The people concerned by the issue of the development of children resulting from the third-party contribution to the parental project are: prospective parents, gamete donors and, particularly, the children resulting from the procedure. Few studies on the fate of children resulting from a donation are able to shed light on their relationship with their parents and with donors involved in the parental project. Indeed, the first studies on children resulting from AP were conducted primarily from an epidemiological perspective. While somatic data are beginning to emerge, very few analyses focus on psychological relationships and on parent-children interactions.<sup>133</sup> This is because clinics only see future parents, and they lose sight of them at birth, not to mention at conception. It is extremely difficult to establish sufficient and statistically valid cohorts. Studies published so far lead to the conclusion that children resulting from AP develop in a way considered normal, while their psychomotor development is not influenced by the mode of reproduction.<sup>134</sup> However, it should be noted that these studies show methodological deficiencies and do not tell us enough about the psychological development of children once they reach adolescence<sup>135</sup> or adulthood.<sup>136</sup>

In this regard, the aspects that seem to cause the most concern and also provoke the most debate are: the child's access to its origins and construction of its family "narrative".<sup>137</sup>

### Filiation: what importance should be accorded to genetics?

The social bond between parents and children is a major component of the problematics related to AP. Practices such as adoption or the restructuring of families after separation and divorce have changed the structure of the traditional nuclear family and have made social filiation more important. While some people attach great value to the genetic bond, others believe that education, feelings and the social and family environment are the most important factors for child development. For example, according to some authors, the use of paternity testing that may undermine a relationship established over the years illustrates the importance of the genetic bond.<sup>138</sup> Other authors, however, consider fatherhood to be primarily a psychological and social phenomenon, focusing on daily interactions and experiences shared with the child.<sup>139</sup> It has been shown that several children have fully blossomed in families that were not on the nuclear family model<sup>140</sup> and that beyond the biological bond, the emotional bond is all-important. The main problem arises when secrecy has been maintained and children only discover the truth later, without having been prepared for this eventuality.

Long before the advent of AP, adoption and the practice of maintaining the confidentiality of the mother's identity at childbirth, particularly in France, have caused a rift between biological kinship and social kinship.<sup>141</sup> This practice enables a woman to give birth anonymously and then give her child up for adoption. Reproductive technologies, in turn, create new ways to "construct" a family and raise children.<sup>142</sup>

However, and paradoxically, with the advent of AP, the “biologization” of filiation has gained momentum:

« As the family structure is always aligned with the social contexts in which it develops, and to the extent that these social contexts are clearly changing (recognition of homosexual marriage, insemination for lesbian couples and single women ...), the importance of biological parenthood could eventually diminish in favour of social parenthood. [...] However, society sends messages that perpetuate the importance of biological parentage. In Belgium, the budget of INAMI [Institut national d'assurance maladie-invalidité or National Institute of Health and Disability Insurance] provides for the reimbursement of treatments like *in vitro* fertilization, which legitimizes their importance for parents concerned. [...] In practice, therefore, we are witnessing the emergence of contradictory trends. More and more adults are raising, at least in part, children with whom they have no biological link. More and more children consider as full-fledged parents adults with whom they have no biological link. A growing number of people are yet willing to seek medical help – and for a number of women this involves a real obstacle course – to conceive “their” children in spite of everything. Although most psychological schools do not acknowledge the existence of a “need or instinct of reproduction”, in one form or another, it seems that many people want to conceive “their own” children.<sup>143</sup>

However, for couples or single people to have a child “of their own”, they must resort to increasingly sophisticated methods or involve a third person in their parental project without this latter contribution being acknowledged. The natural desire<sup>144</sup> to have a child biologically related to them may motivate some people to seek out every means to achieve their end.

Why do people seek genetic filiation? Why is this filiation becoming increasingly important as reproductive technologies are developed? According to one hypothesis, the development of technology leads people to attribute greater value to the genetic bond in relation to the social bond. In this view, the use of available AP techniques thereby ensures that those unable to fulfill their desire for children are now able to exhaust every opportunity to have a child “of their own.”

The emphasis on the biological bond varies from one person to another. People who do not resort to AP or for whom AP did not work may turn to adoption. It even happens that people undertake both adoption procedures and AP in parallel, as a way of maximizing their chances of starting a family.



- 133 M. G. SCHWEITZER and N. PUIG-VERGÈS, “Biotechnologies et filiation. Questions pour l’attachement et la parentalité”, *Annales Médico-psychologiques*, 2002, vol. 160, n°4, p. 333.
- 134 L. RAVEZ, *op. cit.*, p. 55; P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.*
- 135 S. GOLOMBOK *et al.*, “The European study of assisted procreation families: the transition to adolescence”, *Human Reproduction*, 2002, vol. 17, n°3, pp. 830-840.
- 136 P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.*
- 137 M. G. SCHWEITZER and N. PUIG-VERGÈS, *op. cit.*, p. 334.
- 138 Gregory E. KAEBNICK, “The natural father: Genetic paternity testing, marriage, and fatherhood”, *Cambridge Quarterly of healthcare ethics*, 2004, vol. 13, n°1, pp. 49-50.
- 139 *Ibid.*, pp. 53-54.
- 140 Giuliana FUSCALDO, *op. cit.*, p. 167.
- 141 Dominique MEHL, *op. cit.*, p. 292.
- 142 Giuliana FUSCALDO, *op. cit.*, p. 167.
- 143 COMITÉ CONSULTATIF DE BIOÉTHIQUE, *Avis n°37 du 13 novembre 2006 portant sur l’usage des tests d’ADN en matière de détermination de la filiation*, p. 10, [online], [http://www.genethique.org/carrefour\\_infos/textes\\_officiels/titres\\_textes/textes/Avis%20Comit%C3%A9%20consultatif%20de%20bio%C3%A9thique%20-%20Belgique/Avis\\_37\\_ADN\\_Filiation.pdf](http://www.genethique.org/carrefour_infos/textes_officiels/titres_textes/textes/Avis%20Comit%C3%A9%20consultatif%20de%20bio%C3%A9thique%20-%20Belgique/Avis_37_ADN_Filiation.pdf) (our translation).
- 144 According to evolutionary theory, the “need to reproduce” is wired in our genes. All living species must meet with some reproductive success if their species is to survive. Human beings do not appear to be exceptions to this law of nature: “Human beings have always considered it important to survive by having children. Thanks to advances in science, we know that survival is not purely educational, financial or cultural, but is also biological. ‘Our’ gametes have produced ‘our’ children, through whom ‘we’ perpetuate ourselves. [...] Although no-one claims that this relationship is based primarily on the biological link – nothing prevents the father from being just a cultural father – the importance for the child’s psychological equilibrium of knowing about generational filiation feeds the desire to know whether our parents are really our parents.” (*Ibid.*, p. 9) (our translation).

However, the number of adoptions has been declining for three years, whether in Quebec and the rest of Canada or in other host countries. This decrease is probably due to the closure and the tightening of rules for adoption in countries such as South Korea, Haiti and the Philippines.<sup>145</sup> Moreover, the age of adopted children is tending to increase, which may discourage parents who prefer to adopt babies or very young children.<sup>146</sup> The difficulty in adopting children, both in Quebec and abroad, helps direct people towards AP. Prospective adoptive parents may wait several years before the child actually settles in their home. Sometimes they have to repeat the same steps in another country, if the first country has closed the door to foreign adoption. However, AP may also require several years of treatment before leading to the birth of a living child. A certain percentage of parents give up after several cycles of unsuccessful treatment.

In addition, the contribution of a third person to a parental project, whether through egg or sperm donation, maintains the genetic bond between the child and its father, or between the child and its mother. In the case of double gamete donation or embryo donation, two people outside the parental project contribute to the genetic heritage of the child. Where the adoption of already born children is concerned, intentional parents have no genetic link with their child. Once gamete fusion can take place outside the human body, a wide range of combinations can be imagined.<sup>147</sup> These various scenarios are presented below.

#### *The existence of a genetic bond: egg donation and sperm donation*

In a heterosexual couple when the woman is infertile, it is possible to use a donor whose eggs are fertilized by spouse's sperm. In these circumstances, the child will have a genetic link at least with one member of the couple, namely its father. But the father's spouse will also be the one carrying the child, which in turn creates further links. Several factors influence the development of the child *in utero*: the genetic factor is important, but the environment also significantly influences the child's development.<sup>148</sup> Other factors, such as epigenetic\* factors, are not yet well known and also exert an influence.

A study published in 2005 and undertaken in the Netherlands among women who received an egg donation shows that two thirds of them believe the donation has no influence on their emotional attachment with the child. However, it seems to require an ongoing effort for most of them to feel they are real mothers. Nevertheless, because they were pregnant, gave birth to the child and took care of it,<sup>149</sup> many of them say they see no difference with a natural pregnancy.

Where the man is sterile, it may be more difficult for him to establish a bond with the child.<sup>150</sup> In this regard, however, studies reveal conflicting attitudes and observe either the father over-investing in his relationship with the child, or, on the contrary, showing a lack of interest in his parental role.<sup>151</sup> As a result, AID could hinder the attachment process which, in the opinion of child development specialists, is the most powerful factor driving creation of the parent-child bond.<sup>152</sup>

In Quebec society, however, fathers are increasingly involved with their children, as illustrated by the greater number of them taking parental leave.<sup>153</sup> Caution is needed before any assertion is made that the social father involved in AID takes less care of his child than a father who is genetically related to the child. Meanwhile, studies add that children born to lesbian couples develop as well as other children resulting from AP.<sup>154</sup>

In sum, the studies published to date support the conclusion that knowledge of long-term effects of gamete donation on child development remains incomplete<sup>155</sup> and that the lack of a genetic bond between parent and child does not necessarily hinder development of a positive relationship between them.<sup>156</sup>

*The absence of a genetic bond:  
double gamete donation and embryo donation*

In a couple where the man and woman are both infertile, they will have to go through a period of grieving since no biological link with a child is possible.<sup>157</sup> The value of a double gamete donation thus lies in the fact that it allows women to experience and control her pregnancy,<sup>158</sup> create a bond with the fetus and give the “appearance of a biological bond.” There is no consensus about double gamete donation. It is banned in France and some European countries, but is nonetheless authorized in other countries around the world. In Quebec, while double donation is a possibility, the widespread shortage of available gametes means it is a relatively marginal practice.

In the case of embryo donation, pregnancy and childbirth create an authentic bond between parents and child. Moreover, unlike adoption, the child has not known other parents, however briefly, with whom it could have had a shared history or with whom it could have experienced abandonment.<sup>159</sup> However, the fact that another couple have conceived a child may cause the fear that the child will one day meet its biological family.<sup>160</sup> Moreover, as the Commission noted above, people who have surplus embryos generally feel they are “donating their children.” Accordingly, few people are inclined to donate their embryos to another couple or a single person, preferring to provide them for research purposes instead, to destroy them, or to store them in a bank. However, according to one study, directed embryo donation could reduce the anxiety of couples about donating their frozen embryos.<sup>161</sup>

- 145 **SECRETARIAT À L'ADOPTION INTERNATIONALE**, *Les adoptions internationales au Québec en 2007*, Ministère de la Santé et des Services sociaux, Québec, 2008, p. 3, [online], <http://www.adoption.gouv.qc.ca/site/download.php?f=a44d351c40bf6ea310ffb630063a4757>.
- 146 *Ibid.* However, it is likely there could be a revival of this institution, resulting from recent changes to the law on youth protection that seek to limit the total period of placement of young people in order to favour their adoption. See *Youth Protection Act*, R.S.Q. 2006, chap. 34.
- 147 Dominique MEHL, *op. cit.*, pp. 8-9.
- 148 One need only think of the importance of increasing folic acid intake during pregnancy to prevent neural tube defects in fetuses. By contrast, alcohol or drug consumption by the mother can cause birth defects in the fetus.
- 149 D. VAN BERKEL, A. CANDIDO and W.H. PIJFFERS, “Becoming a mother by non-anonymous egg donation: Secrecy and the relationship between egg recipient, egg donor and egg donation child”, *Journal of Psychosomatic Obstetrics & Gynecology*, 2007, vol. 28, n°2, p. 102.
- 150 For example, a research report on the family identity of children resulting from artificial insemination by donor describes the case of a father who said it had taken him several months before he played with his child. The lack of physical resemblance with his child seems to have something to do with it. (Suzanne BEAUDOIN and Francine OUELLET, *L'identité familiale des enfants conçus par insémination artificielle*, Research report, Université Laval, February 1992, p. 46).
- 151 A. MCWHINNIE, “Gamete donation and anonymity – should offspring from donated gametes continue to be denied knowledge of their origins and antecedents?”, *Human Reproduction*, 2001, vol. 16, n°5, pp. 809-811.
- 152 Carol GEORGE and Judith SOLOMON, “Attachment and care giving: the care giving behavioral system”, in Jude CASSIDY and Phillip R. SHAVER (eds.), *Handbook of attachment: theory, research and clinical applications*, New York, The Guilford Press, 1999, pp. 649-670.
- 153 “Since Quebec launched its Parental Insurance Plan, Statistics Canada reports that more than one father in two has requested parental leave. Specifically, the 2006 figures show that in Quebec 56% of eligible fathers requested benefits, compared to 32% in 2005.” (“Pères québécois et canadiens, deux sollicitudes”, *Radio-canada.ca*, 23 June 2008, [online], <http://www.radio-canada.ca/nouvelles/societe/2008/06/23/002-Famille.shtml>) (our translation).
- 154 A. ORGIBET, M.F. LE HEUZEY and M.C. MOUREN, *op. cit.*, pp. 202-210.
- 155 Anne BREWAEYS, “Review: parent-child relationships and child development in donor insemination families”, *Human Reproduction Update*, 2001, vol. 7, n°1, p. 38.
- 156 S. GOLOMBOK *et al.*, “Families created by gamete donation: follow-up at age 2”, *Human Reproduction*, 2005, vol. 20, n°1, p. 286.
- 157 Although some people have proposed the use of reproductive cloning in such cases, this “option” will not be discussed here.
- 158 By controlling diet and stress experienced during pregnancy, women hope to improve their chances of having as healthy a child as possible. With an adoption, it is not possible to know whether the mother’s behaviour may have harmed the health of the child.
- 159 P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.*, p. 3.
- 160 Sheryl DE LACEY, *op. cit.*, p. 1666.
- 161 Giuliana FUSCALDO, *op. cit.*, p. 166.

In view of the fact that embryo hosting programs are little developed to date, the Commission considers it important to pursue studies on the development of children resulting from such donations. Moreover, most available studies involve couples with surplus embryos and very few present the point of view of people without children. Are they interested in this option? Do they consider the lack of genetic bonds as a barrier? Do they have the same concerns as potential embryo “donors”?

Also, as mentioned in Articles 41 and 42 of the *Act on clinical and research activities in assisted procreation*, the Commission believes that scientific studies should be undertaken on the physical and psychological development of children resulting from AP and on the physical and psychological health of women participating in IVF protocols.

*The Commission therefore recommends:*

### **Recommendation No. 1**

- That the Minister of Health and Social Services give the Institut national de santé publique (INSPQ) the mandate to establish a centralized mechanism for collecting non-nominal data in order to monitor the development of children resulting from assisted procreation, as well as the health of persons involved in assisted procreation;
- That this database be accessible to public health officials in fulfilment of the monitoring program, and to researchers whose research projects have been duly approved by the competent authorities, including a research ethics committee.

### **Access to origins: should anonymity be lifted or not?**

In Quebec, gamete donation is normally anonymous.<sup>162</sup> Gamete donors have neither rights nor obligations towards children whose conception results from donated gametes. On the other hand, certain mechanisms make it possible to reconcile the anonymity of a donor with the child’s need to obtain information about the donor. This applies particularly in the case of medical information, knowledge of which may be necessary to protect the life and health of the child. Such mechanisms exist in Quebec and Canada,<sup>163</sup> as well as Belgium,<sup>164</sup> Spain<sup>165</sup> and other states where the law foresees the possibility that the child, its parents and its descendants may obtain non-identifying information in this regard.

However, when anonymity gives priority to respect for the privacy of donors and to secrecy surrounding the circumstances of the child’s birth, by extension, it also deprives the child of the option of gaining access to its origins. According to several observers, the risk of disclosure in inappropriate circumstances of secrets surrounding the birth of children resulting from donations, and the legal impossibility for these children to gain access to information concerning them, come into conflict with the construction of identity, the well-being of the child and the sense of belonging to a family. Moreover, while maintaining the fiction of the biological link between the child and both parents, anonymity ends up denying the genetic contribution made by the donor.

## The interests at stake

Infertility can sometimes be a difficult burden. The popular conception associating fertility with virility may be one of the reasons for the increased use of reproductive technology. This subject is poorly documented in Quebec, and even though well-known public figures are known to have resorted to donated sperm, the fact remains that average Quebeckers are still reluctant to talk about infertility with their colleagues and friends for fear of being ridiculed. In addition, the belief that the inability to have children is linked to “sexual incompetence” seems to linger on. This image may affect the desire of couples to exhaust all possible techniques before turning to donation or adoption because, quite apart from their unfulfilled desire for a child, they feel stigmatized.<sup>166</sup>

For some parents, the anonymity of the donation (the same goes for adoption) somehow helps them to appropriate the child: “[f]rom the perspective of adoptive parents, the fact that the natural parent cannot interfere in the life of the child encourages the development of bonding between them and the child.”<sup>167</sup> Two ways to blur the important role played by the donor, and to leave as much symbolic space as possible to parents, so that they can imitate the standard family, are: making it seem the donation only consists of a single cell and mediating in the clinical setting through the use of medical techniques.<sup>168</sup> “Even though there is a certain movement, relayed through the media, in favour of bringing up the subject of anonymity once again, families are known to find this anonymity reassuring. It protects the parental couple and allows them to construct their parental relationship thanks to a third-party donor who remains very abstract.”<sup>169</sup> The interests of parents and of the child may differ with respect to anonymity: parents see anonymity as a way to protect the family unit, while the child is deprived of the chance to know some of its biological origins:

« All [the couples using donated gametes] (or almost all of them) want to preserve their marital intimacy and avoid the intrusion of a foreign presence in a project of parenthood which is already hard to take all the way to completion. People applying for a donation seem to share the concern that no third party should remain in the procreative landscape. Yet when the question of the child arises, then the benefits of anonymity are weakened. With respect to knowing the donor, the couple’s interests and those of the child begin to diverge. While parents have been protected by anonymity, children can be prevented from living, or rather from forging their identity because they do not know the details about their own history and origins.<sup>170</sup> »

162 Article 542(1) of the C.c.Q. which enshrines the principle of confidentiality.

163 Article 542(2) of the C.c.Q. and articles 18(2) and 18(3) of the federal *Assisted Human Reproduction Act*.

164 According to article 57 of the *Loi relative à la procréation médicalement assistée et à la destination des embryons surnuméraires et des gamètes (Law on assisted procreation and the fate of surplus embryos and gametes)*, the fertility centres must restrict access to any information that could be used to identify the donor. However, non-anonymous donation resulting from an agreement between donor and recipient is authorized. If such is not the case, article 64 of the 2007 law still provides that non-identifying information be transmitted to the persons concerned, that is to say, medical information which could be useful for the child’s health and the physical characteristics of the donor. The same goes for the United Kingdom, where the law has set up a dual desk system: *Human Fertilization and Embryology Act*, 1990, art. 31 © ZA, 31 2 F and 33 B as introduced in the revision of the law in 2008 (*Human Fertilization and Embryology Act*, 2008)

165 In Spain, according to paragraph 5.5(2) of the law of 2006, children resulting from assisted procreation, or their legal representatives, may access information about the donor, but this information must not enable them to identify the donor. Exceptional circumstances that endanger the life or health of the child may permit the lifting of anonymity, if it can prevent danger to the child (*Ley 14/2006 sobre técnicas de reproducción humana asistada*, B.O.E. n. 126 de 27/5/2006, art. 5.5(3)).

166 In some countries, the stigma is very strong, particularly for infertile women. In Nigeria and among Muslims for example, women are generally blamed when a couple is infertile and men can obtain a divorce or become polygamous. In China, not having a child is considered the worst dishonour for a family. In Japan and Korea, infertile women are considered to be made of “stone.” Being infertile in Vietnam means being “poisoned” while Mexican women are considered “incomplete” or “cursed”. (Lynn Clark CALLISTER, *op. cit.*, p. 98).

167 Carmen LAVALLÉE, *op. cit.*, p. 35 (our translation).

168 Victoria M. GRACE, Ken R. DANIELS and Wayne GILLET, *op. cit.*, p. 308.

169 P. REVIDI and B. BEAUQUIER-MACCOTTA, *op. cit.* (our translation).

170 Dominique MEHL, *op. cit.*, p. 272 (our translation).

In this regard, anonymity remains a sort of paradox. On the one hand, the donation ensures a bond of biological filiation between the parents and the child. On the other hand, the donation conceals the fact that the child is biologically related to someone outside the couple. The paradox is that anonymity can both suggest that the biological origins of the child are unimportant and that the emotional bond is what founds the family or, conversely, that biological parenthood is more significant than other forms of kinship to the point where it should be concealed in order to preserve social kinship and family “peace.”

In the opinion of some observers, the anonymity of donor can be likened to a vast unstructured social experiment whose consequences for children have been relatively obscured.<sup>171</sup> Accordingly, there seems to be no evidence that anonymity is the best option considering the interest of the child or family. Children themselves express the difficulties they experience, particularly in the construction of their identity, as well as a certain resentment over the fact that the truth about their real origins has been hidden from them.<sup>172</sup>

A distinction should however be drawn between the question of anonymity and the question of secrecy surrounding the child’s mode of conception, which relates to the parents’ right to respect of their privacy. Yet even in countries where anonymity is lifted, many parents choose to maintain secrecy. Some French and English-language studies estimate that 70% of children whose conception resulted from donated gametes are unaware of the fact.<sup>173</sup> As a result, even when the right of children resulting from AP are acknowledged to have the right to know their origins, a large number of them will never exercise this right.

However, on closer examination, anonymity serves also the interests of adults who did not have to disclose their own infertility rather than the interests of children.

A report of the French Senate in this regard stresses the importance of communication. When the child inherits a complex parentage, difficulties can nonetheless be surmounted provided that the parents do nothing to conceal from the child its family history.<sup>174</sup>

The Commission recognizes that in some cases, because of the family and cultural context in which the child is developing, disclosure is not always in the child’s interest. It considers nonetheless that fertility clinics should routinely offer their customers a form of counselling to help them make an informed decision about the appropriateness of informing the child about the circumstances surrounding its birth. In this regard, counsellors should clearly highlight the potential effects of secrecy on the child and on the whole family.

But anonymity ends up supporting secrecy and in this sense seems paradoxical in a society where the law recognizes the adopted child’s option to gain access to its origins.<sup>175</sup> In the case of adoption, access to origins was recognized as an essential principle once it was realized that even if young children need a strong emotional relationship with their adoptive parents, their quest for identity may sometimes become essential as they get older.<sup>176</sup> In enshrining the anonymity of gamete donors, the law thus creates disparities between adopted citizens and those resulting from AP. However, the aim of equality is to ensure greater well-being of children

and families. This is what explains in part why children resulting from donated gametes are claiming more space in the media and in the courts as they to demand access to their origins:<sup>177</sup>

« The lawsuit claims that the present law discriminates against persons who were conceived as a result of gamete donation. By contrast, adopted children have, by law, certain legal rights and opportunities to know about their biological parents that children conceived by way of gamete donation simply do not enjoy. The lawsuit is based on the guarantees of equality and security of the person in the *Canadian Charter of Rights and Freedoms*.<sup>178</sup>

Also, since the late 1990s, there has been a movement on behalf of the child's interests, which has led several countries to lift anonymity such as the Netherlands (2004), New Zealand (2004), the United Kingdom (2005), Finland (2006) and Belgium (2007);<sup>179</sup> this also suggests that the prospect of a worsening shortage of donors may not be as serious as some fear.

It is conceivable that the profile of donors could change and their numbers could decline; but it is also conceivable that the prospect of gamete donor offspring being able to track down donors could be enough to discourage potential donors. Lifting anonymity and a decline in the number of donors do not necessarily go hand in hand. Indeed, in New Zealand, 10 to 15 years before anonymity was lifted, clinics recruited donors who were willing to be identified eventually by their offspring. The study reveals that a sufficient number of donors were recruited in this way.

For example, a study in the United Kingdom maintains that the best way to recruit "identifiable" donors is through education, by raising awareness of different aspects of the donation (for example, the process, feelings of the donor, recipients and children resulting from the donation).

Finally, note should also be taken of the fact that opinions on this subject can change over time. Thus, if younger donors place more emphasis on the anonymity of their donation, older donors or parents themselves may be more sensitive to the needs of the child with respect to knowing its origin and thus be favorable to lifting anonymity.<sup>180</sup>

The Commission believes in the importance, on the one hand, of ensuring that a balance is achieved between the interests involved and, on the other, of giving precedence to the well-being of the child, while avoiding the creation of disparities between adopted children and those resulting from AP. It believes that it would be wise to proceed one stage at a time.



- 171 Édith DELEURY, "Filiation, parenté, identité : rupture ou continuité?" in *Sortir la maternité du laboratoire : Actes du Forum international sur les nouvelles technologies de la reproduction*, organized by the Conseil du statut de la femme at Montreal on 29, 30 and 31 October 1987 at Concordia University, Quebec, 1988, p. 164; Michelle GIROUX, *op.cit.*; Carmen LAVALLÉE, *op.cit.*; Laura SHANNER, "Legal challenges to donor anonymity", *Health Law Review*, 2003, vol. 11, n°3, p. 25.
- 172 Laura SHANNER, *op. cit.*
- 173 Dominique MEHL, *op.cit.*, p. 247.
- 174 Michèle ANDRÉ, Alain MILON and Henri DE RICHEMONT, "Contribution à la réflexion sur la maternité pour autrui", *Rapport d'information*, Sénat, 2008, p. 63, [online], <http://www.senat.fr/rap/r07-421/r07-4211.pdf>.
- 175 Article 583 of the C.c.Q.: "An adopted person of full age or an adopted minor fourteen years of age or over is entitled to obtain the information enabling him to find his parents if they have previously consented thereto. The same holds true of the parents of an adopted child if the child, once of full age, has previously consented thereto. An adopted minor under fourteen years of age is entitled to obtain information enabling him to find his parents if the parents and the adoptive parents have previously consented thereto. Consent may not be solicited; however, an adopted minor may not be informed of the application for information made by his father or mother."
- 176 Carmen LAVALLÉE, *op.cit.*, p. 25.
- 177 Hélène BUZZETTI, "Enfant recherche donneur de sperme – Un recours collectif historique est déposé pour permettre aux enfants nés de dons de sperme de retrouver leur père biologique", *Le Devoir*, 3 November 2008; Geneviève DELAISI DE PARSEVAL and Pauline TIBERGHEN, "Le don d'embryon, une bombe à retardement", *Libération*, 18 September 2004, [online], <http://genevieve.delaisi.free.fr/pages/don%20d'embryon.html>.
- 178 "For immediate release: First ever class action lawsuit filed by sperm donor offspring in Canada – Court issues injunction to prevent the destruction of records pending the hearing of the lawsuit", 28 October 2008, [online], <http://www.adoption.ca/Donor%20Case%20Press%20Release.htm>.
- 179 Irène THÉRY, *op.cit.*; SÉNAT, *L'anonymat du don de gamètes*, Les documents de travail du Sénat, Série législation comparée, n° LC 186, September 2008.
- 180 Ken DANIELS, "Donor gametes: anonymous or identified?", *Best Practice & Research Clinical Obstetrics and Gynaecology*, 2007, vol. 21, n°1, p. 119.

*Whereas it is better to let gamete donors be the first to lift the anonymity of their donation, instead of proposing a total lifting of anonymity, the Commission recommends:*

### **Recommendation No. 2**

- That the Quebec government amend the Civil Code of Quebec to address the disparity in rights between adopted children and children resulting from donations, with respect to access to their origins, by applying the same practice as in matters of adoption;
- That appropriate counselling be offered routinely, not in a context of self-regulation, but as part of a regulatory framework instead. Such counselling should address both gamete donors and people resorting to donated gametes or embryos, in order to make them aware of the importance for the child of knowing its origins and the implications of lifting anonymity.

### **Respect for the dignity of each human being**

Human dignity is a vague and hard-to-define concept, but is nonetheless a concept at the heart of values professed by democratic societies, including Quebec society. In this regard, and from an ethical perspective, the donation of gametes raises the issue of the instrumentalization of the person.

### **The non-commercialization of the human body and its products**

The Civil Code of Quebec establishes the principle of gratuity in Article 25: “The alienation by a person of a part or product of his body shall be gratuitous; it may not be repeated if it involves a risk to his health.”<sup>181</sup> The Commission rejects outright any idea of challenging the principle enshrined in law of the non-commercialization of human body. However, altruism does not seem to be enough of a motivation to attract a sufficient number of gamete donors to meet the needs of infertile people. Different measures involving some form of monetary exchange have been developed in the context of gamete donation. In order to pursue further analysis in this position statement, the Commission identifies three monetary measures, namely compensation, the payment of an indemnity and the reimbursement of expenses.

#### *Compensation for donors*

Altruism and solidarity motivate donations of gametes and embryos. While these values contribute to protecting the human dignity of donors and of human beings in general, the same cannot be said about the force of attraction exerted by compensation. By compensation, the Commission means the payment to the donor for the product of its body, including payment for time spent making the donation. In such a context, it is difficult even speak of a donation, since the transaction takes on instead the appearance of a sale.

For this reason, the Commission believes such a practice is illegal, and also clearly unacceptable in ethical terms. The Commission recalls that even in the case of organ transplants, compensation for organ donation is not considered acceptable.

### Indemnities for donors

By indemnity, the Commission means payment of a lump sum to all donors as a way of taking into account the costs and time they devoted to making the donation. This however creates a risk of exploitation of the underprivileged and the unemployed for whom such an indemnity would provide a source of income. Furthermore, indemnifying people for lost time poses serious challenges in terms of management and equity: the eggs of women in a high income bracket would require a much greater investment compared to indemnifying women in a low income bracket or who are unemployed. Taking into account the economic interests of female donors would thus militate in favour of resorting to women who are less well off, with the result that such women assume the greater part of the risks of egg donation. The solution is not straight-forward, because most countries having opted for altruistic donation are now facing a shortfall of gamete supply: a parallel market is developing as a result, involving the sale of gametes over the Internet or procreative tourism in countries where laws are more flexible.

Some countries have opted for lump sum indemnities. This is particularly the case in Spain, where egg donors receive about 1,000 euros (about \$1,600) per donation. This payment is considered as a reasonable indemnity for the inconvenience involved, and not as a payment, enabling clinics to avoid breaking the law. Some people consider this indemnity to be an equitable form of compensatory damages which takes account of the physical risk incurred by the donor as well as the inconvenience the donation process may cause in the female donor's personal and family life.<sup>182</sup> However, even an amount of \$1,000 or \$1,500 per donation may encourage poor or unemployed women or female students to "donate" their eggs, which they would never have done had there been no provision for indemnity in the first place. This indemnity may help the woman make ends meet, and thus incite her to donate gametes as a way of commercializing her body and its products.

The shortage of available gametes<sup>183</sup> facing fertility clinics in Quebec makes the issue of indemnifying donors more important. However, "there is no guarantee that the market will actually solve problems that are not fully resolved by the system of gratuity, such as the problem of scarcity, especially since the logic of the marketplace is likely to discourage altruistic donations."<sup>184</sup>

181 C.c.Q., article 25. See also article 7 of the federal *Assisted Human Reproduction Act* which prohibits the purchase of eggs or sperm, as well as advertising for this purpose.

182 G. OROBITG and C. SALAZAR, "The gift of motherhood: Egg donation in a Barcelona infertility clinic", *Ethnos*, March 2005, vol. 70, n°1, p. 34.

183 Official data on the extent of the gamete shortage are rare. However, various sources suggest that such a shortage does exist. For example, three articles in *Le Devoir* mention the shortage of sperm donors: Hélène BUZZETTI, "Les banques canadiennes de sperme sont à sec", *Le Devoir*, 29 and 30 October 2005; Hélène BUZZETTI, "Pourquoi une telle loi?", *Le Devoir*, 29 and 30 October 2005 and Josée BOILEAU, "Manque de dons", *Le Devoir*, 31 October 2005. The first of these articles states that a Quebec clinic has seen the number of donors drop by half since 2004 while another clinic is facing a critical situation. A bank in Toronto has seen the number of donors drop by 71%. The situation would appear to be even worse in the case of egg donors: "The law has hurt sperm banks, but it has dealt a death blow to egg donation." (our translation). The situation seems to be similar in other countries, particularly in France: the Agence de la biomédecine estimates that the number of oocyte donations is too low to meet the demand of couples involved. Waiting times can range up to several years (AGENCE DE LA BIOMÉDECINE, *Le don d'ovocytes*, [online], <http://www.dondovocytes.fr/>).

184 Gilbert HOTTOIS, *op. cit.*, p. 248 (our translation).

### *Reimbursement of expenses*

A third option is to reimburse the expenses incurred by donors when making their donation. Expenses are reimbursed on presentation of receipts and may vary by donor. For some, reimbursement consists of a few dollars, such as the price of a round-trip city bus ticket return, whereas for others, it may involve higher costs (such as gasoline and parking). Costs are higher in the case of egg donation because the donation process is longer, involves more inconvenience and requires an absence from work that can last up to a month.<sup>185</sup>

In its 2005 report, the *Human Fertilisation and Embryology Authority* (HFEA) gave a ruling on the reimbursement of eligible expenses for gamete and embryo donation. Expenses which can currently be refunded are those related to travel, child care and, if the situation requires, accommodation. HFEA also provides that donors may be compensated up to a maximum of £61.28, but shall not exceed the limit of £250 for each donation cycle. In addition, people choosing to donate their surplus embryos could be reimbursed for expenses related to travel to the clinic, for the purposes of signing the consent form and receiving further guidance.<sup>186</sup>

Reimbursement of expenses maintains a certain equity and preserves the altruistic and free character of the donation. Indeed, it is legitimate to doubt whether the expenses incurred in travelling to the clinic hinder gamete donation. On the other hand, such a measure can hardly be considered an incentive to donate. This measure is not the most likely means of increasing the number of donors.

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The Commission has found that this apparently straight-forward question does not easily yield an answer. Indeed, it may at first seem obvious that the non-commercialization of the human body and its products (a principle enshrined in law and consistent with respect for human dignity) should take precedence over all other considerations. However, the value of equity affects various facets of the problematics involved in assisted procreation, and to varying degrees – and this in turn is transforming reflection itself into a true dilemma. The Commission also shares the concern of couples or individuals who wish to obtain a gamete donation and who are somehow penalized by the lack of gametes available to meet their needs. Accordingly, while compensation is already prohibited, should an indemnity package also be prohibited, at the risk of creating inequality between egg donors and sperm donors? Should such an indemnity be allowed instead, at the risk of creating inequality between better-off donors and those less-well-off? Is it acceptable to prohibit a practice likely to increase the number of gamete donors, which could possibly compensate for the shortage of gametes?

Thus, by prohibiting the compensation lump-sum packages for the time and risk involved in the process, egg donors are disadvantaged compared to sperm donors. They lose more time working than their male counterparts, and are exposed to more invasive techniques, more risk and more inconvenience. On the other hand, the reimbursement of expenses strictly related to the donation ensures that poor people will not contribute to meeting the needs of the affluent, by assuming the risks associated with the donation in exchange for an amount of money.

With regard to the concern about the shortage of gametes, the Commission has doubts about the benefits that would accrue from a generous indemnification program. Some signs, for example the fact that many clinics already indemnify donors, suggest that the cause of the shortage is perhaps to be found elsewhere. According to a report submitted to Health Canada:

« It is extremely rare to find any clinic, or in fact any jurisdiction, that says it has sufficient number of gamete donors to meet the demands of third party reproduction. This shortage exists whether gamete donors are paid or not paid. The underlying reason for this is that providing gametes for others to whom you have no previous connection/association is something that comparatively persons wish to do.<sup>187</sup>



This finding strengthens the view that the shortage of gametes in itself is neither surprising nor solely linked to the lack of compensation for donors.

Nevertheless, the Commission believes that not everything should be reimbursed or indemnified, since donation is a personal choice requiring a good dose of altruism. Given that human products are involved, the scarcity of these products should not be invoked as a reason for the use of monetary incentives. A risk-benefit analysis shows that the scarcity of gametes alone (and the benefits of a greater availability of gametes where donations are subject to higher compensation or indemnity) do not constitute a sufficient reason, considering the risks that could arise from compensation or overcompensation of gamete donation (the risks of exploitation, discrimination, commercialization of the human body, health risks for women, etc.). The reimbursement of expenses upon presentation of receipts would attract people who are really interested in the idea of helping infertile people. Moreover, such a practice would prevent donors from disbursing funds in order to make their donation, while acknowledging the action they have taken.

On the other hand, a system of reimbursement would involve a lot of administrative inconvenience for fertility clinics managing it. It could be possible to envisage setting up a bank managed by a central agency, like Héma-Quebec, for example, mandated to take over the management of donated gametes produced in Quebec and, in the event of a shortfall, to obtain sperm from outside of Quebec.

185 See HEALTH CANADA, *Workshop on the Reimbursement of expenditures for Egg and Sperm Donors*, Meeting Report, prepared by the Intersol Group for Health Canada, May 2005.

186 HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA), *Seed Report. A report on the Human Fertilisation and Embryology Authority's review of sperm, egg and embryo donation in the United Kingdom*, London, October 2005, p. 12, [online], <http://www.hfea.gov.uk/docs/SEEDReport05.pdf>; HFEA, *Code of practice, op. cit.*, section 13 (13.2 to 13.4).

187 Valter FEYLES *et al.*, *Altruistic gamete donation. Phase 1*, Research commissioned by the Health and Policy Communication Branch – AHR implementation office, Health Canada, February 2004, p. 5, [online], [http://www.hc-sc.gc.ca/hl-vs/alt\\_formats/hpb-dgps/pdf/reprod/al-gamete-eng.pdf](http://www.hc-sc.gc.ca/hl-vs/alt_formats/hpb-dgps/pdf/reprod/al-gamete-eng.pdf).

*Whereas donation is based on altruism and the non-commercialization of human body is an inviolable principle, the Commission recommends:*

### **Recommendation No. 3**

That the Minister of Health and Social Services establish an agency to regulate approved clinical practices for the storage of gametes and embryos, for recruitment, reimbursement of expenses and the traceability of gamete donors, and for raising awareness of these risks and responsibilities associated with their actions.

#### **The non-instrumentalization of individuals**

Is there a societal obligation to satisfy the desire of infertile people for a child, no matter what the cost? This is the main issue the Commission has raised with respect to the selection of gamete donors by clinics and parents. The Commission also wonders how such a selection could lead to the instrumentalization of persons.

##### *The interests at stake for parents*

In Quebec, the selection of donors is mainly based on physical characteristics. Accordingly, the prospect for parents of selecting the donor on the basis of certain physical criteria allows them to maintain the fiction of kinship while keeping the donation itself secret. Conversely, other people believe that the prospect of choosing the donor, and of learning about some of his/her personal characteristics, would help recipients to speak about the donor to the child.<sup>188</sup>

Although recipients may sometimes wish that other criteria could be evaluated, they are faced with a shortage of available gametes and have to limit their demands.

##### *The interests at stake for children*

The fact of resembling its parents can foster a child's sense of belonging to its self-elected family\*. Additional research will be needed to better define issues related to donor selection based on physical matching with the intentional father. In the past, domestic adoption in Quebec already promoted this matching of parents and children. The emphasis on the resemblance with the parents, however, has evolved over the years, particularly in conjunction with the opening of Quebec to international adoption.

Nowadays, the preponderance of international adoption over domestic adoption has somehow trivialized adoption. Given that foreign children generally have very different physical characteristics compared to their adoptive parents, physical resemblance now seems of less importance than before, at least as regards the profile of parents resorting to adoption. In addition, births outside of wedlock and the transformation of the family unit are now part of the socio-demographic landscape.

As long as practices promote maintaining secrecy about the origins of AP offspring, attitudes are unlikely to evolve towards greater openness. Over time, patterns change and society evolves. However, much as it did in the case of anonymity, the Commission seeks to strike a balance between protection of the privacy – and the autonomy of families – and the interest of children.

In ethical terms, the attempt<sup>189</sup> to determine a maximum number of characteristics for the unborn child could hamper this child's symbolic freedom, namely to be born for itself as a unique individual with its own project. Indeed, from that time on, the question at issue is no longer that of having a healthy child, but of having a child with specific characteristics<sup>190</sup> that meet the expectations of prospective parents. In the United States, prospective parents may consult "catalogues" of sperm donors, choosing a donor based on a pedigree that suits them (education, physical, artistic or athletic skills, etc.).<sup>191</sup> This practice suggests that the child is a consumer product, an object to be customized according to the wishes of parents.

For the Commission, such a practice is unacceptable and amounts to instrumentalizing the unborn child. Even before conception, the hoped-for child is already expected to meet parental expectations. Of course, all parents have legitimate expectations about their offspring. But a huge burden is imposed on the child when reproductive choices are based on the hope that the child will match certain profiles (which, moreover, and according to current knowledge in human genetics, cannot be guaranteed). In addition, such a hope is fostered by the relatively widespread belief that certain talents, skills and abilities can be transmitted through one's genetic make-up.

*Whereas Quebec society should avoid developing practices such as creating "custom-made baby" through the selection of gamete donors, and whereas, under current conditions, the confidentiality of origins is protected and the minimum matching of physical characteristics with the father poses no risk to the child and may even encourage its integration into the family and society, the Commission recommends:*

#### Recommendation No. 4

That the only permissible criteria for donor selection, in addition to medical criteria, be physical criteria for matching with one intentional parent, where this seems to be justified by the welfare of the child.

### The supply of gametes for infertile individuals

Although the Commission gives priority to the interest of the child and the dignity of the human body and its products, it has decided to consider five options for mitigating the effect of any (partial or complete) lifting of anonymity and the impact of freely donated gametes on the offer made to infertile persons: directed donation, paired donation, shared donation, posthumous donation and embryo donation.

188 Guido PENNINGS, "The right to choose your donor: a step towards commercialization or a step toward empowering the patient?", *Human Reproduction*, 2000, vol. 15, n°3, p. 513.

189 Physical characteristics are largely determined by genes, but recessive genes can be transmitted to children, thus reflecting the characteristics present in parental genotypes\*, but absent from their phenotype\*. As for characteristics such as intelligence, athletic or musical ability, nothing proves that they are determined by genes; they could just as well be facilitated by a stimulating family and school environment.

190 Heather WIDDOWS, "Persons and their parts: new reproductive technologies and risks of commodification", *Health Care Analysis*, March 2009, vol. 17, n°1, p. 39.

191 The website of the "Egg Donation" program in California indicates that egg donors must be between the ages of 21 and 30 years, well educated, and of proportionate weight and height. Other agencies have more precise criteria: "Our donors are screened for high intelligence, as measured by high scholastic achievement/ outstanding scores on standardized college and graduate school entrance test". (A PERFECT MATCH, *Egg donation program*, [online], <http://www.aperfectmatch.com/eggdonationprogram.html>).

### Directed gamete donation

In the case of directed donation, the couple or single woman recruits a donor (a sister, friend, colleague, etc.) who provide her own eggs. This type of donation is not anonymous. This gives rise in turn to a number of ethical concerns: do the donors risk being pressured by those around them to donate? What assurance is there that no exchange of money between people is involved? In addition, recipient couples or women may fear that the donor could interfere during pregnancy or become too attached to the child, or that she could one day tell the child all about its status. Conversely, there are cases where donation has strengthened the bond between the donor and the recipient or recipients.<sup>192</sup> The Commission considers that the directed donation of gametes is acceptable as long as donors and recipients receive appropriate counselling so that they may make an informed decision.

#### *Intragenerational and intergenerational donations*

Using donations from within the family raises many ethical issues, including the impact of this practice on the sociological and anthropological foundations of parenthood, and even on the identity of individuals. Two scenarios are possible: intragenerational and intergenerational donation.

An intragenerational donation refers to gamete donation between collateral relatives, that is, between two siblings or within the extended family. This type of gift is generally well accepted, particularly in the United States.<sup>193</sup> In Quebec, one clinic practiced this type of donation, but is no longer doing so. Despite the important issues raised by this practice, there are few studies that determine the effects on children, parents, donors or donors and their families. However, preliminary results are reassuring. Indeed, in some ways intragenerational donation could help keep reproduction within a more traditional setting, while avoiding that the process become completely linked to the medical setting; this in turn could help the child situate the narration of its early life within the family. In addition, knowing who the donor was may allow the child to avoid certain identity problems at a later date, especially during adolescence and when the child becomes a parent in its own right. Finally, the contribution from a related donor could make it easier to reconstitute the social identity of the infertile parent.

However, this type of directed donation should not be allowed to create situations of consanguinity. For example, a woman could not give her eggs to her sister-in-law because they would then be fertilized by the sperm of her brother. This would result in incest and consanguinity (1<sup>st</sup> degree). Confusion about parental figures could not only create conflicts within the family, but also significantly affect the construction of the child's identity, in addition to predisposing it to health problems. It is clear for the Commission that such a practice flies in the face of the child's welfare.

The Commission believes that intragenerational donations require appropriate counselling to ensure that no family pressure is exerted on potential donors and that each party to the donation understands the emotional risks associated with such donations, including risks arising from the rearrangement of the filial bonds.

Intergenerational donation, for its part, is far from being universally accepted. Since it involves the donation of gametes or embryos from one generation of a family to another generation,<sup>194</sup> the incestuous character of the donation constitutes a significant source of discomfort. Moreover, most authors dealing with the donation of gametes from a sociological or anthropological point of view use the argument of incest in opposing this type of donation. According to some of them, the prohibition of incest allows for creation of a genealogical space around the child:

« The dissociation of sexuality and procreation is upsets our notions of parenthood. “To put it very schematically,” says Laurence Gavarini, “our anthropological rules regarding filiation are based on a paradigm of differentiation: gender differentiation, generational differentiation.” This differentiation is challenged by the demands for AP of single women or couples of lesbians and the possible use in assisted procreation of gametes from persons who, on the basis of their order genealogical or the prohibition of incest, could not have sex with each other. This differentiation of the sexes and generations is not a legal construct. Its foundations are anthropological and it also has psychoanalytic resonances.<sup>195</sup> »

This type of directed donation could also be used in the case of a person who wants to freeze gametes for subsequent donation to a member of the family who must undergo chemotherapy to fight cancer. For example, mothers of prepubescent girls undergoing chemotherapy or suffering from a sterility-inducing disease (Turner syndrome, for example) might want to freeze their eggs to give to their daughter when the latter reaches the age of childbearing.<sup>196</sup> Cases of donated gametes between a father and son or between a niece and aunt have been documented.<sup>197</sup>

Family pressure is also a major component of this problematic situation. There may be pressure on the mother to donate her eggs to her daughter (out of guilt or from a sense of duty) and once the opportunity to do so arises, it may seem impossible to backtrack.

Furthermore, intergenerational directed donations could have serious emotional consequences for children because of the resulting confusion in family relationships.<sup>198</sup> In addition, given that the mother may somehow be the grandmother, aunt or sister of the child conceived in this way, temporal and generational boundaries are being transgressed. Theoretically, by means of directed embryo donation, a woman could carry her own brother (for example a couple having kept frozen embryos following fertility treatments could provide its own daughter with surplus embryos). The opposite could also happen, for example in the case where older women used the eggs of their daughter. Some cases of this type have also occurred elsewhere in the world.<sup>199</sup>

- 192 Two Canadian studies tend to corroborate this assertion. The first, conducted in Ontario among 13 egg donors (who donated to their sister, cousin or close friend), reveals that six of them witnessed an improved relationship. (Samantha YEE, Jason A. HITKARI and Ellen GREENBLATT, “A follow-up study of women who donated oocytes to known recipient couples for altruistic reasons”, *Human Reproduction*, 2007, vol. 22, n°7, p. 2044). The second study, conducted in British Columbia among three women who donated eggs to their sister, shows that in all three cases, despite difficulties related to technical aspects of the procedure, the donation brought the two sisters closer and strengthened ties with the donor’s brother-in-law. (Alanna WINTER and Judith C. DANILUK, “A Gift from the heart: the experiences of women whose egg donations helped their sisters become mothers”, *Journal of Counselling & Development*, Autumn 2004, vol. 82, n°4, pp. 483-495). It is interesting to note that both studies conclude that psychological counselling is needed before the donation is made, during the process of donation, and once the donation has been completed.
- 193 Lorna A. MARSHALL, “Intergenerational gamete donation: Ethical and societal implications”, *American Journal of Obstetrics & Gynecology*, June 1998, vol. 178, n°6, p. 1172.
- 194 Jean-Jacques HYEST, “Les nouvelles formes de parentalité et le droit”, *Rapport d’information n°392*, Sénat, 2006, [online], [http://www.senat.fr/basile/visio.do?id=r861549\\_2&idtable=r864499\\_30|r863147\\_14|r861549\\_2|r864196\\_22|r861690\\_43|r859269\\_13|r863048\\_114|r863380\\_10&c=392&rch=gs&de=20060130&au=20090130&dp=3+ans&radio=dp&aff=sep&tri=p&off=0&afd=ppr&afd=ppl&afd=pjl&afd=cvn&isFirs t=true](http://www.senat.fr/basile/visio.do?id=r861549_2&idtable=r864499_30|r863147_14|r861549_2|r864196_22|r861690_43|r859269_13|r863048_114|r863380_10&c=392&rch=gs&de=20060130&au=20090130&dp=3+ans&radio=dp&aff=sep&tri=p&off=0&afd=ppr&afd=ppl&afd=pjl&afd=cvn&isFirs t=true).
- 195 Renée JOYAL, “Parenté, parentalité et filiation. Des questions cruciales pour l’avenir de nos enfants et de nos sociétés”, *Enfances, Familles, Générations*, Autumn 2006, n°5, [online], <http://www.erudit.org/revue/efg/2006/v/n5/015778ar.html> (our translation).
- 196 Mario GIRARD, “Une montréalaise fait congeler ses ovules pour sa fille”, *La Presse*, 16 April 2007, [online], <http://www.cyberpresse.ca/article/20070416/CPACTUEL/704160508/1019/CPACTUALITES>.
- 197 Lorna A. MARSHALL, *op. cit.*, p. 1171.
- 198 *Ibid.*, pp. 1172-1173.
- 199 In Japan, a woman of 61 years carried a child derived from the egg of her daughter and the sperm of her son-in-law, since the daughter had no uterus. (AFP, “Une mère porteuse de 61 ans donne naissance à l’enfant de sa fille”, *Aujourd’hui le Japon*, 21 August 2008, [online], <http://www.aujourdhuilejapon.com/actualites-japon-une-mere-porteuse-de-ans-donne-naissance-a-l-enfant-de-sa-fille-5187.asp?1=1>).

In Quebec, clinics that have received requests for this type of donation vitrified eggs while awaiting clear policies with respect to egg transfer or destruction. Experts at these clinics consider that this is an acceptable practice, provided it is properly monitored to avoid family pressure for the donation. They say this choice of treatment currently involves no medical risk to the patient and is associated with high rates of pregnancies and live births. They also cite the shortage of gametes, which leads many infertile couples to seek a donor among family members; they also say many couples believe a donation from within the family is ideal since it preserves a kind of genetic bond. These experts also note that knowing the origin of the donation allows recipients to feel in control of their reproductive autonomy and avoids the anguish caused by uncertainty related to anonymous donation.<sup>200</sup> While recognizing that new genetic relationships can thus be created, these experts believe that this relatively rare phenomenon likely has minimal impact on society. Finally, they add that families resulting from reproductive technologies such as gamete donation actually reflect the standards of our society.<sup>201</sup>

*Whereas the directed intragenerational donation of gametes may be acceptable if properly monitored, whereas intergenerational directed donation endangers the welfare of unborn children, the Commission recommends:*

#### **Recommendation No. 5**

- That the intragenerational donation of gametes be practiced in an environment that eliminates any possibility of consanguinity;
- That those involved in intragenerational gamete donation receive appropriate counselling so that they may properly assess the potential impact on filial bonds and their relationship with the donor as well as the future relationship between the donor and the child;
- That intergenerational donation be prohibited since it transgresses temporal and generational boundaries.

#### **Paired donation**

Paired donation resembles directed donation except that the donor does not provide her eggs to the specific couple or person recruiting her. Instead, she will be matched with another couple or single person who has recruited a donor. The directed donation and the paired donation thus reach two distinct client groups. Paired donation makes it possible to preserve anonymity while avoiding waiting lists and the potential for interference from the donor in the child's life. However, if a donor withdraws, does not produce eggs or if her eggs are of poorer quality, then the program is thrown off balanced and one of the recipients is wronged. In addition, it is hard to detect possible peer pressure and exchanges of money. The Commission considers that paired donation is acceptable, provided that parties receive appropriate counselling.

#### **Shared donation**

Shared donation programs, such as the one set up in the United Kingdom, aim to convince women and couples who cannot afford to pay for their treatment to donate some of their eggs in exchange for a reduction in the cost of treatment. The question then arises: can cost-sharing be construed as a form of pressure, not to mention of commercialization?

In this regard, HFEA specifies that the only benefits donors can receive are limited to reducing the costs of treatment; the authority adds that in the event that a treatment currently underway fails, a woman cannot give all her eggs in the hope of obtaining an additional lower-cost treatment.<sup>202</sup>

HFEA requires the categorical assurance that women are not subject to any pressure to donate their ova.<sup>203</sup> In the event there are not enough eggs or if some are of poorer quality, HFEA has prepared guidelines for overseeing the distribution of eggs. Thus, the agreement between a fertility clinic, the donor and the recipient must include the minimum number of eggs required to make sharing possible, the number of recipients among whom eggs will be shared, and how they will be shared between the donor and the recipient(s).<sup>204</sup>

Shared donation is not contrary to the interests of the child, but it is of little interest given that first cycles of IVF are reimbursed by the State in Quebec. However, the main interest of this type of donation resides in its having a financial incentive, which runs counter to the principle of non-commercialization of the body, unless egg sharing has an altruistic motivation. In the latter case, it is acceptable, provided that parties receive appropriate counselling.

#### Donation and posthumous insemination

The issue of donation and posthumous insemination was not raised directly by the Minister of Health and Social Services in granting the Commission the mandate to address the ethical issues related to the third-party contribution to the parental project. The Commission nevertheless considered necessary to inquire into this practice, because of the issues this type of donation and insemination could raise for a child in terms of construction of its identity and its development.

In this respect, it is important to carefully define the concept of the parental project. Some criteria can be used to determine whether a couple is truly suited to such a project: do they demonstrate the desire to have and raise a child, do they have the means to bring a child into the world, are they able to take care of the child, both physically and emotionally?<sup>205</sup> Of course, other criteria could be added to this list. To this end, further reflection on the definition of the concept of the parental project could lead to a better assessment of scenarios facing clinicians. For its part, the Commission considers that merely expressing the wish to have children is not a parental project.

200 Guido PENNINGS, *op. cit.*, pp. 508-514.

201 M. M. SEIBEL, M. ZILBERSTEIN and S. G. SEIBEL, "Gamete donation mirrors society", *Human Reproduction*, 1996, vol. 11, n°5, p. 941 and J. ROBERTSON, "Ethical and legal issues in egg donation", *Fertility and Sterility*, 1989, vol. 52, n°3, pp. 353-363.

202 HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA), *HFEA practice guidance note – egg sharing*, [online], [http://www.hfea.gov.uk/docs/Guidance\\_Note\\_egg\\_sharing.pdf](http://www.hfea.gov.uk/docs/Guidance_Note_egg_sharing.pdf).

203 THE LONDON WOMEN'S CLINIC, *op. cit.*, p. 5; see also HFEA, *Code of practice, op. cit.*, section 12 (12.1)

204 HFEA, *HFEA practice guidance note – egg sharing, op. cit.*, pp. 6 and 8. See also HFEA, *Code of practice, op. cit.*, s 12.2.1.

205 Liezl van ZYL, "Intentional parenthood and the nuclear family", *Journal of Medical Humanities*, Summer 2002, vol. 23, n° 2, p. 110.

Four scenarios can be envisaged.

**Gametes from a donor who is now deceased.**

According to this scenario, the donor chose to give his or her gametes to a bank. In the Commission's view, this scenario does not pose a problem since the will of the person concerned is respected. Moreover, it could become difficult to ensure that all donors are still alive at the time of insemination.

**Gametes collected from a man or woman after death.**

In discussing this second scenario, it is worth recalling the case of the mother of an Israeli soldier who wanted the sperm of her son to be taken after his death, for insemination using a surrogate mother.<sup>206</sup> The Commission believes that in this context, precedence should be given to compliance with the previously expressed wishes of the donor. In this regard, it recalls and endorses the principle stated in Article 8(2) of the Canadian *Assisted Human Reproduction Act*, namely that it "No person shall remove human reproductive material from a donor's body after the donor's death for the purpose of creating an embryo unless the donor of the material has given written consent, in accordance with the regulations, to its removal for that purpose."

*Whereas it is possible that this provision may be declared unconstitutional by the Supreme Court on the grounds that it encroaches on the powers of the provinces, the Commission recommends:*

**Recommendation No. 6**

That the removal of gametes from a deceased person be prohibited if the deceased person has not previously consented to it.

The other two scenarios are different from the first two, since they are part of a genuine parental project.

**Collection in fulfilment of a parental project before the death of the spouse.**

This hypothesis concerns a man suffering from a serious illness, who must undergo surgery or chemotherapy or radiotherapy, and who chose to freeze his sperm because of the high risk of infertility.

The Commission considers it appropriate to honour the spouse's wishes, when sperm was collected from the spouse before his death, when he took part during his lifetime in the parental project, and when he consented to posthumous insemination. The Commission notes however that it is important for the deceased's widow to go through a period of reflection before taking a decision on implanting the parental project:

« The fear is that in the weeks following the death, because of her suffering and the influence of relatives, the woman will not be in a state to take a decision involving her future and that of her potential child. Too hasty a decision can hinder the process of grieving, and as a result compromise subsequent reinvestments.<sup>207</sup> »

In the same vein, the case should also be considered of a woman with cancer could have frozen her eggs for later use. When a woman has her eggs collected and frozen before her death, the spouse who wishes to use them for purposes of procreation must then ask a third person to carry the embryo, which then raises ethical and legal issues about the use of a “surrogate mother”, a point which the Commission will address in the next chapter on surrogacy.

### Embryos created in fulfilment of a parental project before the death of the spouse.

Some, such as the Comité Consultatif National d’Éthique pour les sciences de la vie et de la santé (CCNE) (National Consultative Committee on Ethics for Health and Life Sciences) in France, believe that the risks and inconveniences caused by the absence of a father (such as living in single parent families, absence of a paternal model, or lower family income) do not outweigh the benefits associated with the main interest of the child, which is to be born.<sup>208</sup> However, the CCNE believes it reasonable for the decision to transfer the embryo to be taken after a cooling-off period of at least three months, but not exceeding one year.<sup>209</sup>

Others, meanwhile, equate the death of a spouse with the demise of the parental project, and consider that posthumous procreation poses a serious danger to the welfare of the unborn child. This position is taken by members of the Comité consultatif de bioéthique de Belgique (Belgian Advisory Committee on Bioethics), which “gives priority to the principle of the child’s well-being and autonomy, believes that parental freedom to determine the time and methods of reproduction, may be limited.”<sup>210</sup>

In this regard, the psychoanalyst René Diatkine says: “[A]ny child who lives in a family setting very different from those of others experiences significant psychological difficulties whose outcome cannot be predicted. It is hardly reasonable to voluntarily establish such atypical conditions, for reasons unrelated to concern for the welfare of the future child.”<sup>211</sup>

As in the third scenario, the Commission believes that the surviving spouse should go through a minimum period of reflection before the embryo is transferred. In addition, due attention should be paid to pressures possibly exerted by in-laws:

« Case studies conducted as part of posthumous inseminations showed that demands for such a procedure came more frequently from the family of the deceased man than from the widow herself, probably because the parents of the deceased want to ensure there will be offspring after death. In the intergenerational context, one can assume that the child will be able to benefit from the opportunity to identify with the paternal line, but we must consider the impact that pressure from the family circle will have on the widow.<sup>212</sup>



- 206 ASSOCIATED PRESS, “Family of dead Israeli soldier can use his sperm – Court grants parents the right to impregnate stranger with son’s sperm”, *MSNBC*, 29 January 2007, [online], <http://www.msnbc.msn.com/id/16871062/>.
- 207 Francine GILLOT-DE-VRIES, “Insémination artificielle post-mortem”, in Gilbert HOTTOIS and Jean-Noël MISSA (eds.), *op. cit.*, p. 541 (our translation).
- 208 Carson STRONG, Jeffrey R. GINGRICH and William H. KUTTEH, “Debate: Ethics of postmodern sperm retrieval – Ethics of sperm retrieval after death or persistent vegetative state”, *Human Reproduction*, 2000, vol. 15, n°4, pp. 741-742.
- 209 COMITÉ CONSULTATIF NATIONAL D’ÉTHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ (CCNE), *Avis n°40 sur le transfert d’embryons après décès du conjoint (ou du concubin). Rapport*, 17 December 1993, pp. 1-2, [online], <http://www.ccne-ethique.fr/docs/fr/avis040.pdf>, contrary to the position it has also taken on posthumous insemination.
- 210 COMITÉ CONSULTATIF DE BIOÉTHIQUE, *Avis n°19 du 14 octobre 2002 relatif à la destination des embryons congelés*, p. 10, [online], [https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET\\_PG/HOMEPAGE\\_MENU/GEZONDHEIDZORG1\\_MENU/OVERLEGSTRUCTUREN1\\_MENU/COMITEES1\\_MENU/BIOETHISCHECOMMISSIE1\\_MENU/AVIS25\\_MENU/AVIS25\\_DOCS/AVIS19.PDF](https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOMEPAGE_MENU/GEZONDHEIDZORG1_MENU/OVERLEGSTRUCTUREN1_MENU/COMITEES1_MENU/BIOETHISCHECOMMISSIE1_MENU/AVIS25_MENU/AVIS25_DOCS/AVIS19.PDF) (our translation).
- 211 René DIATKINE, “Fécondation in vitro, congélation d’embryons et mères de substitution. Le point de vue d’un psychanalyste”, *Génétique, procréation et droit*, Conference proceedings, Paris, Actes Sud, 1985, p. 279 (our translation).
- 212 Francine GILLOT-DE-VRIES, *op. cit.*, p. 541 (our translation).

Very few studies exist on the subject. However, there is little difference between the situation of children in a single-parent context and children resulting from the insemination of single women.

*Whereas the widow needs to go through a period of reflection, while respect needs to be upheld for the reproductive autonomy of individuals as part of a parental project, the Commission recommends:*

#### **Recommendation No. 7**

That insemination or embryo transfer be permitted only on condition that all the following criteria are met:

- The removal of gametes or fertilization has occurred before death;
- There is written consent of the deceased indicating his or her agreement as provided in their parental project;
- The widow was able to go through a period of reflection and receive adequate counselling in order to make an informed decision.

#### **Embryo donation**

This type of donation is attractive because it is free,<sup>213</sup> yet it is far from a panacea. When people pay storage fees, it is because they generally want to keep their embryos for future use. However, when they stop paying these fees, it may be hard to track them down. Yet, in practice, it seems that very few people actually drop out of sight. In general, however, once individuals and couples have formed their family, they are more emotionally detached from their frozen embryos. In fact, according to one clinic in Quebec, if these people were contacted a few years after the fulfilling their desire for children, it is possible that more of them would want to donate their surplus embryos.

Even when parents gave their consent several years beforehand, a significant proportion of frozen embryos<sup>214</sup> are stored in the banks of fertility clinics, which hesitate to destroy them.<sup>215</sup>

In practical terms, the donation of embryos is a limited alternative so far, given the poor quality of frozen embryos, since the best embryos are still used when they are fresh, by the person(s) for whom they were created. Moreover, the freezing technique has only been improved just recently, which suggests that frozen embryo transfer may meet with a greater rate of success in the future.

It is important that donors and recipients receive professional and independent counselling about the disposal of surplus embryos. This counselling should be available to potential donors in the early steps of assisted procreation so they can prepare for the possibility, on the one hand, of donating their embryos and, on the other hand, of being in a position to provide informed consent without undue influence from anyone.<sup>216</sup>

Whereas the stakeholders involved need to be adequately informed, the techniques for freezing embryos are improving, and embryo donation means that recipients avoid the risks and disadvantages associated with IVF, the Commission recommends:

### Recommendation No. 8

- That people who use assisted procreation receive all information necessary to make an informed decision about embryo donation at an early stage of the process, but also later, when the assisted procreation process has been completed or abandoned and when there remain spare embryos;
- That programs involving anonymous donations of surplus embryos be favoured. To this effect, that people be encouraged after the initial success of assisted procreation to provide their written consent to donate their surplus embryos. After a period of three years, unless the owners of these embryos have made a specific request use these embryos, extend their conservation or destroy them, the embryos should be donated anonymously.

The Commission wishes to clarify that it did not address the fate of “orphan” embryos (which cannot be donated because they are too old) as well as those embryos used for research purposes.

### Prevention and education: acting before the initial stages of assisted procreation

Among people resorting to assisted reproductive technologies, many do so because of infertility or subfertility. Whereas these techniques are rarely the first choice for couples, it is crucial to focus more research on the basic causes of infertility, including the postponement of pregnancy. By taking steps before AP starts, through prevention and education, the Commission considers that demand for AP will likely decrease, thereby reducing the number of people exposed to risks associated with these techniques. More preventive measures should be taken to address male and female infertility.

- 213 Given the high cost of IVF, some people are examining the idea that recipients of surplus embryos reimburse part of the costs of storage and treatment borne by donor couples. The main ethical objection is that such reimbursement would treat human embryos as consumer goods. See on this subject the article by Boon Chin HENG and Tong CAO, “Refund fertility-treatment costs for donated embryos”, *Nature*, September 2006, vol. 443, n° 7107, p. 26.
- 214 As mentioned earlier, these embryos are not all of the same quality, given that conservation methods used in the past are less efficient than vitrification methods in current use.
- 215 Some clinics are reluctant to destroy embryos for which annual storage fees have not been paid, despite the fact that the consent form indicates they shall be destroyed in the event of default or loss of contact. However, when the owners of these embryos have specifically opted for embryo destruction (rather than storage), clinics actually destroy the embryos.
- 216 Boon Chin HENG, “Letter to the Editor: Independent counselling on embryo donation for infertility patients”, *Human Reproduction*, 2007, vol. 22, n° 8, pp. 1-2.

Strategies should be developed in this area, with a view particularly to better inform women about the relationship between age and fertility. The fact that more women are postponing the age of first pregnancy for professional or personal reasons may have a significant impact on the demand for AP:

« I ask, in fact, that women be told the truth: by waiting for the ideal man, the ideal home, the ideal moment in terms of their career, they run the risk of not being able to have children because their fertility is decreasing. I'm sorry for all these women I meet, who, for various reasons, believed they could have children later on, and who leave my office in tears when I tell them that it will not be possible. I ask that we stop lying to these women and stop maintaining false hopes.<sup>217</sup> »

In this regard, Canadian demographics statistics show that the average age of women at childbirth continues to rise, reaching 29.6 years of age in 2005. It was 27.2 years in 1970 and 27.8 in 1990.<sup>218</sup>

However, in a society that carries the myth of “a child when I want and if I want,” where the desire for children is postponed and where the offer of assisted procreation is ever-present<sup>219</sup> (AID, IVF, ICSI, gamete donation, embryo donation, surrogacy, and all their variations thereof), people may consider any drive for “prevention” as a limitation of their reproductive autonomy. This claim of autonomy leads to increased demand for access to AP services in order to “bypass” infertility problems.

Regarding the relationship between age and fertility, it is worth mentioning that the later age at which people procreate is a socio-cultural phenomenon characteristic of our times:

« And this time delay does not result from a whim or star-like vanity or wonderwoman. It really stems from a contemporary evolution of societies towards family planning and from the well-known aspiration of women nowadays not to be assigned the role of motherhood, but to live it as a personal existential choice.<sup>220</sup> »

In addition, despite all possible prevention and education, there will always be cases of unexplained or unavoidable infertility. However, physicians like Dr. Joëlle Belaisch-Allart advocate that people stop lying to women about the real chances of pregnancy at an older age:

« Women were first deluded by the famous family planning slogan: “a child when I want.” This was a way of highlighting the new possibilities of birth control offered by the contraceptive pill: but contraception means I won't have a child when I do not want to, and not having one when I want one. The shortcut is misleading and women have allowed themselves to be fooled. [...] I would conclude this way: what we, fertility specialists, want to avoid is suggesting to women that it is easy to get pregnant after 40 years. That's not true. It's great if you're lucky enough to get pregnant, but it's a lie to make women believe that they just have to the age of 40, that they just have to want a child to become pregnant, that life will be a bed of roses. And I think that if women were warned about this, some would change their career plans, to fulfill their project of motherhood a little earlier, when they take it to heart. I also know it is not easy to get this message to women, because they might take it as some kind of macho statement. As a woman, I probably am more likely to be heard. I say that all those women who want to focus on their careers continue to do so if they truly wish and if they do not want to have a child at any cost; but

that those who have a true desire for a child realize that it is better find a way to balance career and motherhood before the age of 40, because after that the chances of getting pregnant are tiny. Let the gynecologists play their role and warn women. I hope we set up a prevention campaign to avoid expectations and disappointments: when women are warned of the risk they will never get pregnant, then they will choose to act with full knowledge of the facts.<sup>221</sup>



Other themes could also be raised during awareness campaigns. For example, the fact that sexually transmitted infections are likely to cause infertility or that fertility decreases with age.

*Whereas prevention may take the form of public policies aiming to raising awareness among the population of the causes of infertility and the risks of childbearing at a later age, the Commission recommends:*

#### Recommendation No. 9

- That the Minister of Health and Social Services fund a public awareness campaign on the known causes of infertility and the ways to preserve fertility;
- That the Quebec government reinforce socio-economic measures and public policies that incite people to engage in parental projects at an earlier age;
- That the Quebec government fund research programs on the prevention of infertility.

Another facet of the involvement of a third person to parental project is to be treated. In some cases the only remedy available is a person outside the parental project whose role is that of surrogate. The next chapter demonstrates the Commission discussion on the topic.

217 Interview with Dr Joëlle BELAÏSCH-ALLART, “Un bébé après 40 ans : le premier risque est de ne jamais devenir enceinte”, 29<sup>e</sup> journées du Collège National des Gynécologues et Obstétriciens Français, December 2005, [online], <http://www.gyneweb.fr/Sources/fertilite/jba2.htm> (our translation).

218 STATISTICS CANADA, *Report on the Demographic Situation in Canada – 2005-2006*, Ottawa, 2008, Description for Figure 2.2, [online], <http://www.statcan.gc.ca/pub/91-209-x/2004000/part1/figures/desc/desc-f2-2-eng.htm>.

219 The phenomenon of the advancing age of women at first pregnancy could lead to increased access to egg vitrification. This technique could be seen as the guarantee of continued fertility.

220 Dominique MEHL, *op. cit.*, p. 41 (our translation).

221 Interview with Dr Joëlle BELAÏSCH-ALLART, *op. cit.* (our translation).





SURROGACY: MAINTAINING  
THE LEGAL *STATUS QUO*

## SURROGACY: MAINTAINING THE LEGAL STATUS QUO

Surrogacy<sup>222</sup> generally includes all situations where a woman goes ahead with a pregnancy, not because she intends to keep the child and take on the social role of mother, but in order to hand the child over, at birth, to a person or a couple with whom she has contracted for this purpose. “From a human point of view, it consists of a transfer of the child from the family of the woman giving birth to the applicant parent, and from a legal point of view it consists of a transfer of rights and specific duties towards the child.”<sup>223</sup>

Surrogacy is presented as a procreative option in cases:

- where a woman is physiologically unable to become pregnant<sup>224</sup> or where pregnancy poses a substantial risk to her own health or that of the child;
- where a woman chooses to have a child (whether biologically related to her or not) but does not wish to assume gestation (for social, professional or other reasons);
- where a single man or living as a couple with another man wants a child to whom he is biologically related.

Unlike egg donation, *in vitro* fertilization and preimplantation genetic diagnosis, the practice of surrogacy can very take place without any medical intervention. In fact, surrogacy appeared well before medicine and biology were in a position to provide support to infertile couples.<sup>225</sup> But it has become increasingly popular because the development of technology now allows for procreation without sexual intercourse, and medical supervision of gametes provides a sense of security.

New kinds of surrogacy are emerging nowadays. The most common kind is where the surrogate mother is inseminated with sperm from the spouse of a woman who can neither conceive nor carry a child. In this case, the egg used is provided by the surrogate mother. In fulfilling the roles both of genitor and of gestator, this woman may thus be considered in so many words a “substitute mother”.<sup>226</sup> A homosexual couple may also consider recourse to a substitute mother. The semen of one of the homosexual partners is then used for intra-uterine insemination of the surrogate mother.

With the development of assisted procreation, a new form of substitute motherhood has emerged: one in which the eggs of the surrogate mother are not used for fertilization and where the surrogate mother is solely a gestational mother. In this situation, an embryo already conceived *in vitro* is transferred into the uterus of a woman who will carry and give birth to it, on behalf of the couple or person whose gametes were used or, in some cases, who have resorted to donors. The embryo transferred may come from:

- *in vitro* fertilization of the ovum of the woman intending to raise the child and the sperm of her spouse;
- the ovum of the woman intending to raise the child and donor sperm;
- from an egg donor and sperm from the man who intends to raise the child;
- from an egg donor and sperm donor.

222 Some terminological clarifications are needed here: in Canada, the English term commonly used is “surrogacy”, but “surrogate motherhood” also exists although many other terms are commonly used in the literature such as “substitute mother”, “pregnancy contract”, “womb for rent”, and “pregnancy proxy”. An additional clarification: in this position statement, the term “traditional surrogacy” is used when a woman (a third party) is inseminated with her own eggs which have been fertilized by spouse’s sperm from the couple; the term “gestational surrogacy” is used when a woman is inseminated with fertilized eggs from another woman; in a generic sense, the terms “surrogacy” and “surrogate” are used. For additional terms, see also footnote 226.

223 COMITÉ CONSULTATIF DE BIOÉTHIQUE, *Avis n°30 du 5 juillet 2004 relatif à la gestation-pour-autrui (mères porteuses)*, Belgique, Ministère de la Santé publique et des Pensions, 2004, p. 4 (our translation).

224 For example, women with Rokitansky syndrome (Mayer-Rokitansky-Kuster-Hauser or MRKH) are born without a uterus or vagina. Others will have to undergo a hysterectomy\* because of a health problem.

225 “[...] already in ancient Rome, surrogacy was an accepted custom, the term ‘ventrem locare’ was used to describe the process that allowed to seek the services of a fertile woman who would give a child to a woman who was sterile or given birth to stillborn children. Biblical examples are often cited as evidence of the existence of this practice at a very early period. Thus, according to a long historical tradition from Roman families to wealthy bourgeois families in nineteenth century Paris, surrogate mothers have always existed. This practice has survived the ages to reappear in a desexualized form, as a last resort for infertile women.” (Nathalie MASSAGER, “Gestation pour autrui” in Gilbert HOTTOIS and Jean-Noël MISSA (eds.), *op. cit.*, p. 483 quoting François TERRÉ, *L’enfant de l’esclave*, Paris, Flammarion, 1987 (our translation)).

226 Although the literature on this point is rather confusing. Some authors, contrasting this situation with the one where the surrogate is not the genetic mother (*gestational surrogacy*) speak of *straight surrogacy*. Others, however, qualify this situation as *partial surrogacy*, while the opposite situation is described as *full surrogacy*. See Peter R. BRINSDEN, “Gestational Surrogacy,” *Human Reproduction Update*, 2003, vol. 9, n° 5, pp. 483-484. For additional terms, see also footnote 222.

It is important to understand that in such cases, the woman has no genetic bond with the child she carries for a third person. This is also why IVF tends to be used rather than insemination of a surrogate mother with the spouse's sperm, in order to prevent the surrogate mother from becoming too attached to the child.

In Quebec, there is very little documentation about surrogacy since the contracts providing for it are not binding and have no legal value: in the eyes of the law, these contracts are absolutely null and therefore unenforceable.<sup>227</sup> This means that couples or individuals who use the services of a surrogate mother take a significant risk because, legally, the surrogate mother cannot be forced to hand over the child once pregnancy reaches term. In the same vein, the surrogate mother for her part cannot invoke the existence of the contract in order to claim any sums due from the signatories or any other form of compensation which may be described in the document.

## THE LEGAL FRAMEWORK

In Quebec, surrogacy contracts are therefore not recognized in law. They are considered unlawful, because they are contrary to public order.<sup>228</sup> This is also the case in several countries including Germany,<sup>229</sup> Belgium,<sup>230</sup> France,<sup>231</sup> Spain,<sup>232</sup> Italy,<sup>233</sup> the Netherlands, Switzerland<sup>234</sup> and some American states<sup>235</sup> where there is no federal law in this area and where the matter falls within the competence of individual states.<sup>236</sup> Such consideration is based on values, but also the rules of law:

« Whatever the classification used to denote the contract of surrogacy, its validity is challenged under the following rules of law: [...] 4) the right of the woman to establish her filiation with respect to the child to whom she gives birth, which recognizes every woman's inalienable right to establish her motherhood with the respect to the child she brings into the world, without anyone being able to force her to relinquish this maternity in one way or another, such that a gestational surrogate mother's contractual commitment to relinquish this right in advance is null and void.<sup>237</sup> »

However, while surrogacy contracts are considered unlawful and therefore unenforceable in civil law, they may not strictly speaking be illegal, in other words, punishable by fines or imprisonment. Indeed, the Canadian *Assisted Human Reproduction Act* criminalizes certain practices, but does not prohibit substitute motherhood *per se*;<sup>238</sup> the act only prohibits payment for substitute motherhood, payment of intermediaries, or the placing of advertisements to obtain the paid services of a surrogate mother.<sup>239</sup> On the other hand, the law prohibits members of the medical profession from assisting a female person to become a surrogate mother, where they know or have reason

- 227 Article 541 of the C.c.Q.: “Any agreement whereby a woman undertakes to procreate or carry a child for another person is absolutely null.”
- 228 The solution was already recognized, even before the legislator introduced a specific provision to that effect in the Civil Code.
- 229 *Law on family mediation with respect to adoption (Gesetz über die Vermittlung der Annahme als Kind und über das Verbot der Vermittlung von Ersatzmüttern, 1989)*, art. 13(d) and *Law on the protection of the embryo (Svensk Författningssamling, Föräldrabalk, 1990)*, art.1 (7).
- 230 Although there is no specific provision to this effect, these contracts are considered absolutely null, since they are contrary to public order. See COMITÉ CONSULTATIF DE BIOÉTHIQUE, *Avis n°30 du 5 juillet 2004 relatif à la gestation-pour-autrui (mères porteuses)*, *op.cit.*, p. 9, which is based on articles 6 and 1128 of the Belgian Civil Code.
- 231 Art. 16-7 of the French Civil Code. Those serving as intermediaries between a couple wishing to host a child and a woman agree to carry this child through pregnancy and to hand it over to them may face penalties (art. 227-12 of the Penal Code). The applicant couple may itself be prosecuted on charges of incitement to abandonment (*ibid.*) voluntary substitution, simulation or dissimulation causing a breach of the civil status of the child (art. 227-13 of the Penal Code).
- 232 *Law of May 27, 2006 on Assisted Reproduction Technology (Ley 14/2006 sobre técnicas de reproducción humana asistida, BOE n. 126 of 27/5/2006)*, art. 10.1.
- 233 Italy prohibits any contribution of a third person when using AP techniques, including surrogacy: *Law n° 40 of February 19, 2004 on Medically Assisted Procreation (Nuove norme sulla procreazione assistita: vietata the fecondazione eterologa, Legge 19.02.2004 N° 40, GU 24.02.2004)*, art. 4(3).
- 234 *Federal Law on Assisted Reproduction of December 18, 1998 (Loi fédérale sur la reproduction assistée du 18 décembre 1998)*, art. 4. See also articles 119, 122 and 123 of the Federal Constitution of the Swiss Confederation of 18 April 1999.
- 235 This is the case in Kentucky, Indiana, Louisiana and Nebraska. Other states, such as Arizona, Michigan, New York, New Mexico, Utah and the District of Columbia, have ruled that acting as a paid intermediary in a case of surrogacy is a penal offence. See Michèle ANDRÉ, Alain MILON and Henri DE RICHEMONT, *op. cit.*, pp. 24-25.
- 236 Some states have adopted specific provisions concerning the establishment of filiation and the transfer of parental rights, but in the absence of such provisions, it is the Courts which, following common law (methods of establishing filiation, custody of children, forfeiture of parental authority) will rule on the rights of all parties. In California, where the activities of intermediaries are particularly widespread, in the event of conflict between the genetic mother and the woman who carried the child, both of whom, by law, have equal claims to the title of mother, priority is given to the parental project. See Michèle ANDRÉ, Alain MILON and Henri DE RICHEMONT, *op. cit.*, p. 32; Marie-Christine KIROUACK, “Le projet parental et les nouvelles règles de la filiation: une avancée ou un recul quant à la stabilité de la filiation?”, in *Développements récents en droit familial*, Cowansville, Éditions Yvon Blais, 2005, pp. 469-472; Flavia BERY, “Interpreting a Rent-A-Womb Contract: How California Courts Should Proceed When Gestational Surrogacy Arrangements Go Sour”, *California Western Law Review*, 2005-2006, vol. 42, p. 321; Ina PANTELEJEVA, “Are surrogate mother contracts enforceable?”, *International Journal of Baltic Law*, 2005, vol. 2, n° 3, p. 15; Anthony MILLER, “Baseline, Bright-Line, Best Interests: A Pragmatic Approach for California to Provide Certainty in Determining Parentage”, *McGeorge Law Review*, 2002-2003, vol. 34, n° 3, p. 637; R. B. SHARMA, “Forensic considerations of surrogacy – an overview”, *Journal of Clinical Forensic Medicine*, 2006, vol. 13, n°2, p. 82.
- 237 Nathalie MASSAGER, *op. cit.*, p. 485 (our translation).
- 238 The law does not, however, retain the term, but uses that of surrogate mother instead, defining it as follows: “female person who — with the intention of surrendering the child at birth to a donor or another person — carries an embryo or foetus that was conceived by means of an assisted reproduction procedure and derived from the genes of a donor or donors.” This means it does not cover situations where there were sexual relations between the surrogate and the “donor” or cases where pregnancy resulted from a private donation, even though these practices were accompanied by payment.
- 239 *Assisted Human Reproduction Act*, art. 6, the constitutionality of which was not challenged by the Government of Quebec. In 2005, 103 cycles were undertaken in Canada involving the transfer of an embryo into the uterus of a woman other than the one intending to raise the child. Of these cycles, 78 involved using eggs from the intentional mother (49 involved IVF + ICSI and 29 involved the transfer of frozen embryos). Other cycles used donated eggs instead (17 IVF + ICSI and 8 transfers of frozen embryos). Sperm donation was used in a single cycle (Joanne GUNBY *et al.*, *op. cit.*, pp. 1721-1730).

to believe she is under 18 years of age.<sup>240</sup> Although the act presents the practice *a contrario*, the practice is nonetheless subject to control and, in some way, is legitimized by federal law.<sup>241</sup> Consequently, *a priori*, a dichotomy exists between criminal and civil law, which has had the effect of causing some confusion between what is void and what is illegal, for clinicians practicing in this area.

This situation is not unique however. Indeed, in most countries, like Canada, surrogacy for altruistic reasons is not prohibited by law, the contract providing for surrogacy is not enforceable as such: “the substitute mother is always the legal mother and it is only later, with her consent, that filiation may be modified.”<sup>242</sup> This is the case particularly in the United Kingdom<sup>243</sup> and the Netherlands,<sup>244</sup> countries in which the transfer of parental rights is governed by law and not on the basis of the contract. In Canada, on the provincial level, this is also the case in Alberta.<sup>245</sup>

## THE CONTEXT OF PRACTICE

In Quebec, only two clinics offer a surrogacy program.<sup>246</sup> The clinic consulted in the course of this position statement only offers *in vitro* fertilization of the couple’s gametes (surrogacy program). This program is offered to women whose ovaries are functioning normally but who have no uterus or who have medical problems that may pose a risk to pregnancy. Following a request for recourse to a surrogate mother, the couple meets the medical team which conducts examinations aimed at establishing the inability of the woman to carry a child.<sup>247</sup>

This clinic does not perform any recruitment activity and the program requires that couples seeking a surrogate mother must find her themselves. The surrogate mother must be aged 18 to 35 years, receive a positive psychological assessment, be healthy and have a balanced and stable life (she must not consume alcohol, drugs or tobacco). In general, it seems that women who volunteer are usually young, unemployed and primarily motivated by altruistic feelings.<sup>248</sup> Moreover, couples seeking to resort to a surrogate mother would seem to often be of advanced age and of above average social and economic status.

As with all programs requiring a third-party contribution to the parental project, a request for using a surrogate mother is only accepted by the clinic if the couple and the person they have recruited meet the clinic’s psychologist together. As part of the surrogacy program, the team wants to ensure that the parties have come to an agreement about the following questions, without making moral judgments about the nature of the responses:

- Will amniocentesis be performed? If so, and if it reveals that the baby has an abnormality, will abortion be resorted to?
- What are the opinions of different parties regarding multiple pregnancy and selective reduction in the number of fetuses?
- What will happen to embryos that may be frozen?
- To what extent will the applicant couple have something to say about the lifestyle of the surrogate mother during pregnancy?
- Which of the surrogate mother’s expenses will be covered by the applicant couple?

- Will the child have a relationship with the surrogate mother and her children? If so, what kind of relationship?
- Is the potential surrogate mother motivated solely by altruistic reasons?
- Is the potential surrogate mother aware of the risks inherent in any pregnancy?
- Do both parties understand that the child will have to be adopted by the applicant after birth, and that, in the event the surrogate mother changes her mind, any pre-existing contract will have no legal validity?

240 *Assisted Human Reproduction Act*, art. 6 (4).

241 Marie-Christine KIROUACK, *op. cit.*, p. 465. The law even provides the conditions under which the surrogate mother may be reimbursed for expenditures incurred during pregnancy (on presentation of receipts) and the resulting loss of work-related income if it is established to be for health reasons, whereas any other form of payment remains prohibited (*Assisted Human Reproduction Act*, art. 12, according to which reimbursement must be made in accordance with the regulations and a license; these regulations had not yet been adopted when the Court of Appeal of Quebec ruled on the constitutionality of the federal law). It should be noted here that this provision is among articles declared unconstitutional by the Court of Appeal, and that the decision of the Supreme Court is still pending.

242 Michèle ANDRÉ, Alain MILON and Henri DE RICHEMONT, *op. cit.*, p. 29.

243 “No surrogacy arrangement is enforceable by or against any person making it.” Quoted from the *Surrogacy Act, 1985*, article 1A, as amended by the *Human Fertilisation and Embryology Act: Human Fertilisation and Embryology Act, 1990*, art. 36 (1). According to this latter law, “the woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child” (*Human Fertilisation and Embryology Act, 1990*, as amended in 2008 (*Human Fertilisation and Embryology Act, 2008*), art. 33 (1)). However, when an embryo was created with the gametes of at least one spouse to be implanted into the uterus of a surrogate mother, the law provides for the possibility of using a special procedure (*Parental Order*) which allows under certain conditions (including the consent of the gestational mother), to establish a bond of filiation between the child and the authors of the parental project. The law specifies

that the consent of the surrogate mother cannot be given before a period of six weeks after birth has passed (*Human Fertilisation and Embryology Act, 1990*, art. 30). This amounts, in fact, to a procedure of accelerated adoption, since the *Parental Order* has the same effects (*Human Fertilisation and Embryology Act, 1990*, as amended by the law of 2008, art. 54; see also articles 42 to 45 of the law as well as the Code of practice of the agency responsible for its implementation: HFEA, *Code of practice, op. cit.*, ch. 14 (*Surrogacy*)). See also Jacqueline LAUSS-DIEM, “Maternité de substitution et transfert de parenté en Angleterre”, *Revue internationale de droit comparé*, 1996, vol. 48, p. 855 and Frédérique GRANET-LAMBRECHTS, “Maternités de substitution, filiation et état civil. Panorama européen”, *Droit de la famille – Revue mensuelle Lexisnexis, Jurisclasseur*, 2007, n° 12, pp. 7-10.

244 Regulations of 1 April 1998 relating to institutions that practice *in vitro* fertilization and in reference to the guidelines of the Dutch Netherlands Association of Obstetrics and Gynecology. These guidelines specify that the commissioning parents must be informed that the surrogate mother who, legally, is the mother of the child, may decide to keep it. See SÉNAT, *La gestation pour autrui*, Les documents de travail du Sénat, Série Législation comparée, n° L.C. 182, pp. 23-24.

245 *Family Law Act*, S.A. 2003, c. F.45, article 12 allows the genetic mother to obtain, within 14 days after the birth of the child and if the woman who carried the child so consents, a judicial declaration to the effect that she is the legal mother. Under this provision, any convention reached before this request was made, between the parties relating to the transfer of parental rights, is deemed null. Following this declaration, the genetic mother is considered the mother from the birth of the child onward.

246 Nathalie PARENT, “Tableau sommaire des établissements offrant des services de fertilité au Québec”, in *Répertoire des services de planning des naissances*, Fédération du Québec pour le planning des naissances (FQPN), 2008.

247 In 2007, approximately 50% of couples who requested the use of surrogacy presented the medical indications required by this medical clinic. In the case of patients who have a uterus but have been deemed unsuitable for pregnancy, and before starting the process, the protocol followed by the team says they need to provide a letter from a specialist confirming the diagnosis.

248 Valter FEYLES *et al.*, *op. cit.*

According to experts consulted, all these issues concerning the relationship between the couple and the person volunteering for surrogacy are mainly discussed in private, outside the clinic, before meeting with the team. The psychologist and the medical team taking the decision to proceed with IVF based their decision on the fact that there was consensus on each of these points between the parties, but does not seek to know the precise content of the agreement. Some teams advise the parties, before any medical procedure, to establish a contract in due form specifying the various aspects of their relationship during pregnancy and after birth – even though such a contract is legally invalid.

Once the procedure is approved by the clinic, the IVF protocol can begin, as described in the section on egg donation in the previous chapter. Just as in the case of egg donation, the spouse and the surrogate mother must both be treated by hormone therapy in order to coordinate and synchronize the treatment cycles of the two women so that the uterus of the surrogate mother is ready to receive the embryos just days after fertilization. Physiologically, the surrogate mother does not run more risks than the woman undergoing IVF treatment. Like all women subjected to such treatment, the surrogate mother may experience complications during pregnancy and have to undergo a caesarean section, for example.

For the time being, the practice of surrogacy is somewhat limited in Quebec, as the clinic consulted stated that in 2007 only two surrogate mothers underwent IVF treatment,<sup>249</sup> and in this program only one birth was reported.<sup>250</sup> It is however possible that Quebec couples may have resorted to surrogates abroad, just as Quebec women may have been recruited by people living abroad to carry their child. Given the lack of data in this regard, it is not possible to assess how high the demand for surrogates is, or to determine what agreements are being concluded and what the real motivations of surrogate mothers are.

Yet, as difficult as it is to measure the scope of surrogacy, the practice exists here as elsewhere, as is shown by a recent judgment of the Court of Quebec,<sup>251</sup> and it raises a number of ethical issues.

## ETHICAL ISSUES

The issues at stake are much the same as those the Commission has identified for gamete donation, with one exception. It may be difficult for the child to establish who its parents are, and this may become a source of conflict, even to the point where the child has no status, in other words the child is without either mother or father. For the child, surrogacy constitutes a major issue, quite apart from the difficulties the child may face in having two mother figures. In the Commission's view, the well-being of the child is the primary value to be considered and goes to the heart of the issues raised by surrogacy. However, the practice of surrogacy also affects other values, including women's health and autonomy, and the dignity of the human person, which involves the principle of the non-commercialization of the human body.

## The status of the child

In Quebec law, motherhood is determined by the birth of a child<sup>252</sup>, which is duly recorded in an attestation of birth;<sup>253</sup> motherhood cannot be challenged on the grounds that the egg or embryo is not from the woman who carried the pregnancy to term.<sup>254</sup> It is from this attestation of birth and the subsequent declaration of birth,<sup>255</sup> signed by the parents, that the birth certificate is established, providing normal proof of filiation.<sup>256</sup>

Based on these premises, three scenarios are possible: the surrogate mother decides to keep the child; she hands it over to the prospective parents – and in so doing, she fulfils her obligation to them; or, finally, none of the actors involved wants to keep the child and it is left without status.

### The surrogate mother decides to keep the child.

Again, several situations can be envisaged.

If this woman is married or in a civil union, pursuant to the law her spouse is presumed to be the child's father, even when she did not declare who the father was.<sup>257</sup> In these circumstances, her spouse may have to prove his non-paternity,<sup>258</sup> but he also may choose not to contest it, which makes him the legal father.

The situation may also arise from a different angle. The biological father, whose sperm was used to artificially inseminate the surrogate mother, may also recognize his paternity and make a declaration to this effect in the child's civil status.<sup>259</sup> In this context, both parents to whom the child is genetically related could contest the other's custody rights, a scenario in which "the child rarely comes out the winner of transactions concerning it",<sup>260</sup> even if the court, when called on to make a decision, makes such a decision based on the child's interest.<sup>261</sup> One can imagine the tension that the child may be subject to, to the extent that it results from the parental project developed by its father and his spouse, not with its biological mother, who is also its legal mother. Whatever the outcome of the suit, both parents remain holders of parental authority and, in the event of conflict concerning important decisions,<sup>262</sup> it is once again the court that must decide.

249 During each of these cycles, two embryos were transferred into the uterus of the surrogate mother.

250 In the United States, the births of about 1,000 children per year involve surrogate mothers. The cost of gestation through an agency apparently ranges from US\$60,000 to US\$ 100,000. See Michèle ANDRÉ, Alain MILON and Henri DE RICHEMONT, *op. cit.*, p. 33.

251 *Adoption-091*, (2009) R.J.Q. 445 (QCCQ).

252 Jean PINEAU and Marie PRATTE, *op. cit.*, p. 684; Michelle GIROUX, "L'encadrement de la maternité de substitution au Québec et la protection de l'intérêt de l'enfant", *Revue générale de droit*, 1997, vol. 28, n° 4, p. 542.

253 This document establishes the place, date and time of birth, the sex of the child as well as the name, address and place of birth of the mother (article 111 of the C.c.Q.).

254 Mireille D. CASTELLI and Dominique GOUBAU, *op. cit.*, p. 197; Benoît MOORE, "Quelle famille pour le XXI<sup>e</sup> Siècle: perspectives québécoises", *Revue canadienne de droit familial*, 2003, vol. 57, pp. 63-67.

255 Articles 112 to 115 of the C.c.Q. In principle, they may declare the filiation with respect to them (maternity for the mother, paternity for the father). However, if they are married or in a civil union, one of them may declare the filiation with regard to the other.

256 Articles 523 and 538.1 of the C.c.Q.

257 Article 525 of the C.c.Q.

258 Marie-Christine KIROUACK, *op. cit.*, pp. 475-476, which draws here on article 539 of the C.c.Q.

259 *Ibid.*, pp. 467.

260 *Ibid.* (our translation).

261 Article 33 of the C.c.Q., paragraph 1, while paragraph 2 states: "Consideration is given, in addition to the moral, intellectual, emotional and physical needs of the child, to the child's age, health, personality and family environment, and to the other aspects of his situation."

262 Jean PINEAU and Marie PRATTE, *op. cit.*, pp. 855-859; Mireille D. CASTELLI and Dominique GOUBAU, *op. cit.*, pp. 333-343.

Finally, the genetic father could not recognize the child, in which case the surrogate mother, in her capacity as guardian, could bring an action to claim status in order to establish his paternal filiation. She could not prove this status by relying on the existing agreement concluded with the biological father,<sup>263</sup> or even to request a genetic test. In such circumstances, the establishment of paternity remains uncertain, to say the least.<sup>264</sup>

#### The surrogate mother delivers the child to the applicant person or couple

In this context, for the child carried by this woman to be recognized as the child of the couple, adoption must be resorted to. The surrogate mother may well give her consent to the child's adoption by the spouse of the biological father, as provided in Article 555 of the Civil Code of Quebec.<sup>265</sup> This is also the only way to establish a parental relationship with the mother if the social mother is also the genetic mother, or with both members of the couple, if the child results from a double gamete donation.<sup>266</sup> But should people be allowed to do indirectly what they cannot do directly?

“Two principles are in conflict here, the *a priori* interest of the child and the *a posteriori* interest of the child.”<sup>267</sup> For most authors, if the *a priori* interest of the child – which determines the framework for surrogacy – aims to discourage this practice and requires that the regularization of this situation not be facilitated, it remains the case that a child is born, and that its *a posteriori* interest may require that individuals who really want to assume the role of parents can do so.

« By analogy with the natural child of times gone by, who for too long was discriminated against, we should avoid the child born as a result of a surrogacy agreement being subjected to the same fate. Indeed, this latter child should not suffer prejudice as a result of its parents' behaviour. For this reason, courts have no alternative but to allow adoption by special consent, if the other requirements of the law are met.<sup>268</sup> »

By not discriminating between a child born to a surrogate mother and a child resulting from the adultery of one of its parents, the solution would thus also be consistent with the values expressed in the *Convention on the Rights of Child*.<sup>269</sup> Although this document is not directly applicable in domestic law, it may nevertheless serve as a guide for courts to interpret the law.<sup>270</sup> The adoption of the child by special consent would also enable the surrogate mother to “see her identity preserved, which would make eventual reunion possible.”<sup>271</sup>

Accordingly, unless a flaw relating to parental consent is ascertained,<sup>272</sup> or if it is not in the child's best interest, adoption by special consent should remain a possible option.<sup>273</sup> One may consider solutions as simple adoption as provided for in draft legislation amending the Civil Code relating to adoption and parental authority, tabled in October 2009.

### The child who does not meet expectations

The risk that the child could be rejected by its future parents should not be ruled out, especially if the child does not meet expectations, in the event of disability or illness for example, and where its biological mother refuses to assume responsibility.

263 Michelle GIROUX, *op. cit.*, p. 545.

264 Article 535.1 of the C.c.Q. provides that, on the application of an interested person, the court will be authorized "to order the analysis of a sample of a bodily substance so that the genetic profile of a person involved in the action may be established". However, the court may only issue such an order when a commencement of proof of filiation has been established by the person having brought the action or unless the presumptions or indications resulting from facts already clearly established by that person are sufficiently strong to warrant such an order (the physical resemblance of the child and the interested person, for example). See Mireille D. CASTELLI and D. GOUBAU, *op. cit.*, pp. 216-222; Jean PINEAU and Marie PRATTE, *op. cit.*, pp. 653-659.

265 Under the Civil Code of Quebec, "no adoption may take place except in the interest of the child and on the conditions prescribed by law" (article 543). Among these conditions features the consent of the father or mother. This consent may be general or special, and according to terms of article 555 of the C.c.Q., special consent may be given in favour of the spouse of the father or mother.

266 The surrogate mother may also not declare her maternity, in which case special consent may be given by the biological father (and also the father declared in the civil status) in favour of his spouse. The solution is however more questionable, since the maternity of the mother, even if it appears on the attestation of birth, will not in principle appear on the birth certificate.

267 Michelle GIROUX, *op. cit.*, p. 543 (our translation).

268 *Ibid.*, p. 544 (our translation); Jean PINEAU and Marie PRATTE, *op. cit.*, pp. 684-685 which based their view on the ruling in the case *O.F. c. J.F.*, [2005] R.D.F. 475 (C.Q.). However, see Carmen LAVALLÉE, *L'enfant, ses familles et les institutions de l'adoption*, Montréal, Éditions Wilson & Lafleur, 2005, according to whom each of these solutions is unsatisfactory (pp. 405-413).

269 Ratified by Canada on December 13, 1991 and coming into force on January 12, 1992, the International *Convention on the Rights of the Child* guarantees the right of the child who has been temporarily or permanently deprived of its family to protection and special assistance from the State. This solution would also be consistent with article 7 of the Convention, according to which the child shall, as far as possible, have the right to know and be cared for by its parents, when the adoptive parents are also its genetic parents (art. 20) (<http://www2.ohchr.org/english/law/crc.htm>).

270 *A.P. c. L.D.*, (2001) R.J.Q.16 (C.A.)

271 Benoît MOORE, "Les enfants du nouveau siècle (libres propos sur la réforme du droit de la filiation)", in *Développements récents en droit familial*, Cowansville, Éditions Yvon BLAIS, 2002, p. 97 (our translation). This solution would also comply with article 7 of the *Convention on the Rights of the Child*.

272 To illustrate such a flaw, see *Adoption-091*, (2009) R.J.Q. 445 (CCQC), in which case the maternity of the surrogate mother had not been declared in the civil status, and where the father had given special consent to the adoption of his daughter by his spouse. The court before which the existence of an agreement, together with the payment of a sum of \$20,000 had been admitted, refused to grant the adoption on the grounds that accepting the father's consent "would mean that under the circumstances, the court was wilfully blind and was confirming that the end justifies the means." (paragraph 77 of the ruling).

273 Some provinces have adopted specific provisions in this regard. In Ontario, the surrogate mother, under certain conditions, may consent to the adoption of children by prospective parents (*Child and Family Services Act*, R.S.O. 1990, C.11, articles 137 (i) f), 146.2 and 149; see also *Children's Law Reform Act*, R.S.O. 1990, C. 12, article 12(2)). In Nova Scotia, the *Birth Registration Regulations* allow the court to make a declaratory order with respect to the parentage of the child in favour of its intended parents under certain conditions. Several elements must be proven, however: parents must have initiated the parental project and they must intend to be parents of the child; the agreement must have been planned before the child's conception; and the child must be genetically related to at least one member of the couple (*Birth Registration Regulations*, N.S. Reg. 390/2007, art. 5).

In such an event, the only possible outcome for the surrogate mother is to place the child with a family that eventually would be ready to adopt it with its disability. Again, if the adoption is a curative solution in the child's interest, "[it] also highlights the rationale for the *a priori* prohibition of this practice."<sup>274</sup> Since the mother may still not declare her filiation to it, even if it is hard for her to hide her maternity,<sup>275</sup> the child will remain one born of unknown parents.<sup>276</sup>

Determining the status of a child is therefore not without consequences for its development, and the fact that it can be faced with two maternal figures is a challenge in itself.

### The development of the child

Contrary to egg donation, surrogacy can create another type of cleavage in motherhood: the social mother<sup>277</sup> may be the genetic mother, although she is not the one carrying the child:

« These two gifts of motherhood – genetic and gestational – differ in the sense that, in oocyte donation, the social mother – who is also the uterine mother – carries and feeds the baby from the embryonic stage, thus sharing with a fetus to which she is not genetically related a certain category of bodily fluids (blood, oxygen, placenta). Unlike surrogacy where [...] another cleavage operates.<sup>278</sup> »

There exists in this respect a dual discourse on assisted procreation and surrogate motherhood. In the case of AP, emphasis is laid on the importance or legitimacy of the mother's desire to carry the child herself (rather than adopt it), whereas in the case of surrogacy, emphasis is laid on avoiding any talk of the importance of the bond established during pregnancy between the surrogate mother and the fetus.

Surrogacy therefore highlights a dichotomy, a distinction between the woman carrying the fetus and the fetus itself. Surrogacy underlines the idea that the fetus is a being "apart" from the woman carrying it, and this in turn potentially has consequences for the well-being of the woman and the child she carries. Some even argue that it is possible that the surrogate mother set up a psychological barrier between herself and the fetus, because the latter is not his child. Such detachment may lead to behaviours that could endanger her health as well as that of the fetus.<sup>279</sup>

According to some observers, the child's healthy development would seem to depend on the environment provided by the parents and the love they lavish on the child. For others, the permanent abandonment of the child at birth by the woman who brought it into the world is somehow irreparable. This theory of the importance of the early relationship established between mother and child during pregnancy does not meet with universal acceptance, however:

« The unborn child is necessarily in a fusional relation with the woman carrying it: it gets used to her body, her smell, her voice and the presence of people around her. However, if the reality of exchanges between the embryo (and the fetus) and the mother during the nine months of pregnancy is well established, the effects of these exchanges are still not clear. [...] Actually, it is very difficult to build a solid theory on the influence and nature of prenatal exchanges, since they depend on each woman and appear to be singular. A multitude of cases are witnessed in the clinic: some women are only attached to the child during pregnancy, others cannot stand gestation and only love their child once it is born, others again have no problematic relationship with pregnancy... these observations prove that pregnancy does not make the mother.<sup>280</sup>

Moreover, to date “no scientific study of the practice considered has demonstrated the potential for damage to the child, in terms of prenatal psychology.”<sup>281</sup>

It is important to note once again that while the studies published so far are reassuring, there are still few longitudinal studies devoted to the long-term effects on children resulting from surrogacy arrangements. Most research has focused on the feelings experienced by surrogate mothers after handing over the child and the relationships they can maintain thereafter with the parents and child. There is thus not enough data to draw meaningful conclusions.<sup>282</sup>



- 274 Michelle GIROUX, *op. cit.*, p. 546 (our translation).
- 275 Édith DELEURY and Dominique GOUBAU, *Le droit des personnes physiques*, 4<sup>th</sup> ed., Cowansville, Les Éditions Yvon BLAIS, 2008, p. 335.
- 276 Jean PINEAU and Marie PRATTE, *op. cit.*, pp. 600-601; Mireille D. CASTELLI and Dominique GOUBAU, *op. cit.*, p. 199, referring to article 116 of the C.C.Q.
- 277 There are several ways to describe parents “other than biological or genetic”: social, intentional or intended, and adoptive.
- 278 Geneviève DELAISI DE PARSEVAL, *Famille à tout prix*, *op. cit.*, p. 116 (our translation).
- 279 “It has been proposed that surrogate mothers may tend to distance themselves from the unborn baby, believing that the child they carry is not theirs. Such a detachment may make them more likely to put themselves and the unborn child's health at risk. (Vasanti JADVA *et al.*, “Surrogacy: the experiences of surrogate mothers,” *Human Reproduction*, 2003, vol. 18, n° 10, p. 2196).
- 280 Michèle ANDRÉ, Alain MILON and Henri DE RICHEMONT, *op. cit.*, pp. 60-61 (our translation).
- 281 Nathalie MASSAGER, *op. cit.*, p. 484 (our translation).
- 282 Peter R. BRINSDEN, *op. cit.*, pp. 486-487; Geneviève DELAISI DE PARSEVAL, “To FIV or not to FIV: la gestation pour autrui, future indication d'assistance médicale à la procréation?”, *Gynécologie Obstétrique & Fertilité*, 2006, vol. 34, n° 9, pp. 722-724.

According to some psychiatrists, children having to cope with several maternal figures may have difficulty in resolving potential conflicts arising from this situation and may find it difficult to fulfill themselves. Particularly during adolescence, a child resulting from surrogacy may feel, in a conflictual way, a contradictory sense of dual loyalty, on the one hand, towards the woman who brought it into the world and, on the other, towards the intentional parents who wanted it and who consider it as their own.<sup>283</sup>

« This conflict may be all the more violent in that the child, unlike abandoned children, cannot consider that the woman who carried it handed it over to its intentional parents out of love. Abandoned children in fact often treat the wound of abandonment by considering, when possible, that they were abandoned out of love, and that their parents hoped they would have a better future if they were entrusted to other adults whose had an easier life. In the case of children resulting from surrogacy, this psychological strategy is not an option, since the surrogate mother hands the child over, to comply with a straightforward agreement with the intentional parents, and not out of love.<sup>284</sup> »

The situation may be all the more complex, given that in surrogacy, several actors are involved, which raises the question of anonymity and access to the origins

### Access to origins

As a reminder, surrogacy can take several forms:

- 1) the intentional parents provide gametes and the surrogate mother only carries the child (gestational surrogacy);
- 2) the egg is provided by a donor and the father provides the sperm;
- 3) the mother provides the egg while the sperm is provided by a donor;
- 4) the egg and sperm are both provided by donors;
- 5) the surrogate mother provides the ovum which is fertilized by the father's sperm (traditional surrogacy);
- 6) the surrogate mother provides the ovum which is fertilized by donor sperm.

Motherhood can be distributed between two or three women and paternity attributed to one or two men, involving a total of three to five distinct individuals in the conception of a child.<sup>285</sup>

In this context, should secrecy be maintained or should the focus be placed on truth about the child's origins? A way should be found to decide whether it is better for the child to be aware of its origins or whether the secret should be kept, while bearing in mind all the implications that such secrecy can have on the child's life. Here again, as in the case of gamete donation, the power of words is important and parents should be encouraged to reveal the circumstances surrounding the birth of the child.

However, the issue of the secrecy of origins and of anonymity takes on particular dimensions in cases of surrogacy, since it is based on an agreement between parties. A surrogate mother may end up intervening in family life. There are also documented cases where the surrogate mother has kept in touch, mainly with parents, but sometimes with children who see her as a “nanny.” A 2003 study was undertaken in England with 42 couples who had a one-year-old child with a surrogate mother; according to the study 91% of mothers and 93% of fathers saw the surrogate mother at least once following the birth. The surrogate mother saw the child again in 76% of cases. About 60% of couples continue to see the surrogate mother a few times a year and in most cases the relationship would appear to be harmonious. Among cases where the surrogate mother has seen the child, 92% of mothers and 90% of fathers see the surrogate’s involvement in the child’s life positively.<sup>286</sup>

These studies do not however say how children perceive their filiation at a later age. The issue is particularly important given that the surrogate mother, in some cases, may herself be part of the family, which also raises questions of another order, such as the autonomy and health of woman who accept to carry the child for someone else.

### Women’s health

Among the risks to the physical health of the surrogate mother may be noted the possibility of miscarriage, ectopic or multiple pregnancy and medical complications that increase with the age of the mother and the complexity of her reproductive history.<sup>287</sup> A woman is not required to have a child and she can decide not to, but may she legitimately transfer that risk to another woman, especially if she is resorting to surrogacy for non-medical reasons?<sup>288</sup>

The surrogate mother may also be subject to risks to her psychological health. For example, in “handing over the child” she carried to the couple who desired it, she may experience suffering and mourning. A study conducted in 2003 on the experiences of surrogate mothers, suggests that surrogate mothers do not experience particular difficulties in handing over the child and that the emotional problems experienced in the weeks after birth decrease over time.<sup>289</sup> However, some observers point out that about 10% of surrogates appear to need therapy after handing over the child to its social parents.<sup>290</sup>

- 283 Michèle ANDRÉ, Alain MILON and Henri DE RICHEMONT, *op. cit.*, p. 62.
- 284 *Ibid*, p. 63 (our translation); the authors are here quoting Professor Marcel RUFFO, child psychiatrist and supervisor of the adolescent unit of Sainte-Marguerite University Hospital in Marseille.
- 285 Theoretically, it would be possible for five people to be the “parents” of a child. For example, the child could be conceived from a donated embryo, the latter being implanted into the uterus of a surrogate mother. Thus, the child would have three mothers (one genetic, one gestational and one intentional) and two fathers (one genetic and one intentional).
- 286 Fiona MacCALLUM *et al.*, “Surrogacy: The experience of commissioning couples”, *Human Reproduction*, 2003, vol. 18, n° 6, p. 1339.
- 287 F. SHENFIELD *et al.*, “ESHRE task force on ethics and law 10: Surrogacy”, *Human Reproduction*, 2005, vol. 20, n°10, p. 2705.
- 288 Sometimes women lose their reproductive capacity by removal of the uterus following pregnancy. See Dan R. REILLY, “Surrogate pregnancy: a guide for Canadian prenatal health care providers”, *Canadian Medical Association Journal*, 13 February 2007, vol. 176, n° 4, pp. 484-485.
- 289 Vasanti JADVA *et al.*, *op. cit.*, p. 2196.
- 290 Brendan OSBERG, “For your first born child: An ethical defense of the exploitation argument against commercial surrogacy”, *Penn. Bioethics Journal*, Spring 2006, vol. 2, n°2, p. 45.

## Women's autonomy

Surrogacy underlines the idea that the fetus is a being “apart” from the woman carrying it, and this in turn potentially has consequences for the autonomy of the pregnant woman. The Commission is concerned that women who act as surrogate mothers no longer have the autonomy normally accorded to a mother carrying her child. Indeed, prospective parents do not necessarily focus on the well-being of the surrogate mother, but rather on the well-being of the unborn child. And even if prospective parents do show concern about the woman's well-being, how can one be sure that it is as a “gestator” rather than as a person? Moreover, prospective parents may exert pressures on various aspects of the situation, such as the surrogate's lifestyle, monitoring of pregnancy and childbirth. She must also submit to procedures and examinations offered by the medical team and adopt behaviour conducive to development of a healthy child.

This separation of the pregnant woman and the fetus is problematic for the whole community, because it calls into question the foundations underlying the right to abortion, and to the integrity, security and autonomy of women.<sup>291</sup> In the Commission's view, reproductive autonomy is established and cannot be questioned, and it is up to the surrogate mother, and to her alone, to take decisions regarding the development of pregnancy, particularly if she eventually signalled her desire to seek an abortion.

Finally, in the event that the surrogate is a friend or sister of an adoptive parent, additional risks of pressure may arise, leading to delicate situations and psychological difficulties for the people concerned. Relationships existing before pregnancy can have positive or negative impacts on the contractual relationship. In addition, unlike the case of a “foreign” surrogate mother with whom parents may decide *a priori* to break off all contact following the child's birth, a surrogate mother who becomes an aunt, or who remains within the close circle of friends of the “adoptive” couple cannot be easily pushed aside after birth. An additional psychological challenge therefore resides in the way relations are managed between the adoptive couple and the surrogate mother, on the one hand, and between the child and the surrogate mother, on the other hand.<sup>292</sup>

## The non-commercialization of the body and the non-instrumentalization of persons

Surrogate mothers may find satisfaction in helping a couple have a child: they do not derive a direct benefit, beyond the feeling of having helped a couple fulfill their project of having a child. Other women may become surrogates simply for the pleasure of being pregnant.<sup>293</sup> Still others become surrogates in order to make money,<sup>294</sup> while some see it as a way to escape poverty and even to bring some dreams and life projects to fruition.<sup>295</sup> Thus, surrogacy entails the potential exploitation of women, especially of poor women.<sup>296</sup> In this sense, the Canadian law banning commercial gestation can be compared to the law prohibiting the sale of organs because there is a huge potential of coercion and society has an obligation to ensure that no individual should be forced to sell or lease part of his or her body.<sup>297</sup>

It is important to distinguish here so-called “commercial” surrogacy, for which the surrogate is paid,<sup>298</sup> and so-called “altruistic” surrogacy which involves women agreeing to carry a child for a sister or a friend simply out of solidarity, with only maternity-related expenses being reimbursed.<sup>299</sup> Surrogacy may require the surrogate mother to incur many medical and other pregnancy-related expenses. In Canada, it should be remembered that all pregnant women are covered by government programs providing for preventive withdrawals, medical and maternity leave. Pregnant women also benefit from regular medical monitoring. There is no discrimination between surrogate mothers and other pregnant women, in terms of access to services provided by the health-care system.

In this context, the reimbursement of expenses upon presentation of receipts would have the effect of avoiding the prospect of financial gains, while sparing surrogate mothers the need to bear other pregnancy-related costs on their own. However, payment of remuneration (a lump sum payment) could discriminate between women, since it could make it seem more advantageous to carry a child on behalf of others than for oneself. Hence the importance for women contemplating surrogacy to be well-informed about the risks they face; to understand that all pregnant women face these risks; while the risks themselves should not easily be assigned monetary values. Thus, by choosing to carry a child for others, a woman is entitled to reimbursement of certain expenses, but she should also be made aware that not everything can be refunded and that her choice inevitably involves a degree of altruism.

In addition to the risk of exploitation of the woman and her body, surrogate motherhood poses a risk to the child who somehow becomes a commodity that can be bought or sold.<sup>300</sup>

291 Vanessa MUNRO, “Surrogacy and the construction of the maternal-foetal relationship: the feminist dilemma examined”, *Res Publica*, January 2001, vol. 7, n° 1, pp. 26-35; Melody CHEN, “Wombs for Rent: an Examination of Prohibitory and Regulatory Approaches to Governing Preconception Arrangements”, *Health Law in Canada*, 2003, vol. 23, n° 3, p. 45.

292 This is also why in some countries, India for example, where contracts for surrogacy are lawful, but are also regulated, individuals are prohibited from contracting with fertility clinics when these individuals are related to the intentional parents or are close to them. See B.R. SHARMA, *op. cit.*, p. 82.

293 Such stories are sometimes the subject of articles in newspapers or magazines, for example in *Le Soleil*: “34-year-old Laurie Rioux, the spouse of Jessica’s godfather [a woman who cannot carry a child without risking her life and that of the fetus] wanted to relive a pregnancy. But the woman from Saint-Jean-Port-Joli does not want another child. She is completely fulfilled by having a seven-year-old daughter.” (Laurie RICHARD, “Mère porteuse pour bébés-espoirs”, *Le Soleil*, 24 September 2008) (our translation).

294 In an article on surrogate mothers in India, one woman admitted having done it for the money. (REUTERS, “Rent-a-womb trend fuels debate – American couples head to India for cheaper fertility services”, *MSNBC*, 5 February 2007, [online], <http://msnbc.msn.com/id/16988881/print/1/displaymode/1098>).

295 Melinda BECK, “Ova time: women line up to donate eggs – for money”, *The Wall Street Journal*, 9 December 2008.

296 B.R. SHARMA, *op. cit.*, p. 83.

297 Brendan OSBERG, *op. cit.*, p. 45.

298 In the United States, the Surrogacy Solutions agency offers between US\$15,000 and US\$20,000 per gestation when the surrogate mother provides her ova and between US\$14,000 and US\$18,000 when she is only gestational surrogate (<http://www.surrogacysolutions.net/mothers.htm>).

299 Brendan OSBERG, *op. cit.*, p. 42.

300 B.R. SHARMA, *op. cit.*, p. 81.

## Cross-border reproduction

Canadians and Quebeckers go abroad every year to procure assisted procreative services that are not available here, or are too expensive. Conversely, and for similar reasons in their country of origin, people living abroad come to Canada.<sup>301</sup> For their part, donors also move from one place to the next, in order to get a better price for their gametes.<sup>302</sup>

Cross-border reproduction (commonly called “procreative tourism”) is disturbing for several reasons: it is only an option for people who can afford it; all control of quality or of security of services offered is impossible – which may pose risks for mothers and children; and it involves and increases the risk that women living in developing countries will be exploited by more affluent foreigners. In addition, since legal prohibitions are generally a reflection of social consensus, it is disturbing that some people circumvent the laws of one country to go to another, where laws are more lax. Procreative tourism also underlies the notion that human reproduction is an object of commerce. The terms “baby business” and “reproductive industry” also illustrate this integration of human reproduction into the domain of commerce.

Some people believe laws should be strengthened, making this type of tourism illegal. Others see an opportunity to harmonize laws and ease legislation so that people can go satisfy their desire for a child wherever this is possible and then return home. Finally, others see this practice as a guarantee of fairness and autonomy for prospective parents.<sup>303</sup> In Europe, the legislative differences between countries are even more striking given their great geographical proximity. These differences are mainly due to positions taken by established political parties, as well as the influence of religions and traditions.

Procreative tourism does not only occur between countries with similar economic status and different legislative frameworks. Some American and European couples will probably seek out “lower cost” surrogate mothers in poorer countries, for example in Eastern Europe, India or other parts of the world where the exploitation of women is not a social issue: “Fifty women from Anand in India and thus carrying the children for couples from the United States, Taiwan, the United Kingdom and elsewhere, in exchange for what they consider is a very high sum of money but which is actually a relatively modest sum for couples: these latter generally pay less than \$10,000.”<sup>304</sup> Some people question whether these poor women, struggling with food and social insecurities, actually have freedom of choice, in accepting to alleviate this suffering by agreeing to carry a child for payment. The reproductive autonomy of these women here enters into conflict with the non-instrumentalization of human beings and the non-commercialization of human body. The Commission is concerned about the social injustice and poverty affecting thousands of women worldwide, and believes that the best way to help them is not to subject them to a new form of exploitation.

A question also arises about the responsibility of physicians with respect to procreative tourism. When physicians know that their patients may be tempted to resort to a more open country, should they close their eyes or should they guide their patients towards more acceptable solutions instead? Are they in effect complicit, when making a technical intervention, for example conducting an ultrasound for a woman they know has bought eggs abroad? Can the medical act be dissociated from the whole process of assisted procreation? While doctors have a duty to care for their patients, they should not encourage procreative tourism.

The argument of procreative tourism is invoked each time AP is regulated. The Commission believes that in addition to going against the values of society, easing the laws would do nothing to solve the problem. In the Commission's view, yielding to this temptation is not an acceptable option.

In Quebec, although the practice of surrogacy is not recognized, it is nevertheless practiced on a small scale. It is difficult to measure its impact on surrogate mothers, children and the resulting families, because few studies have been conducted on the subject. It is therefore important to exercise prudence and to limit the practice in the interest of all parties involved.

*Whereas surrogacy entails risks of exploitation of women that are ethically unacceptable and considering that such a practice would lead to a form of reification of the child that the Commission cannot endorse.*

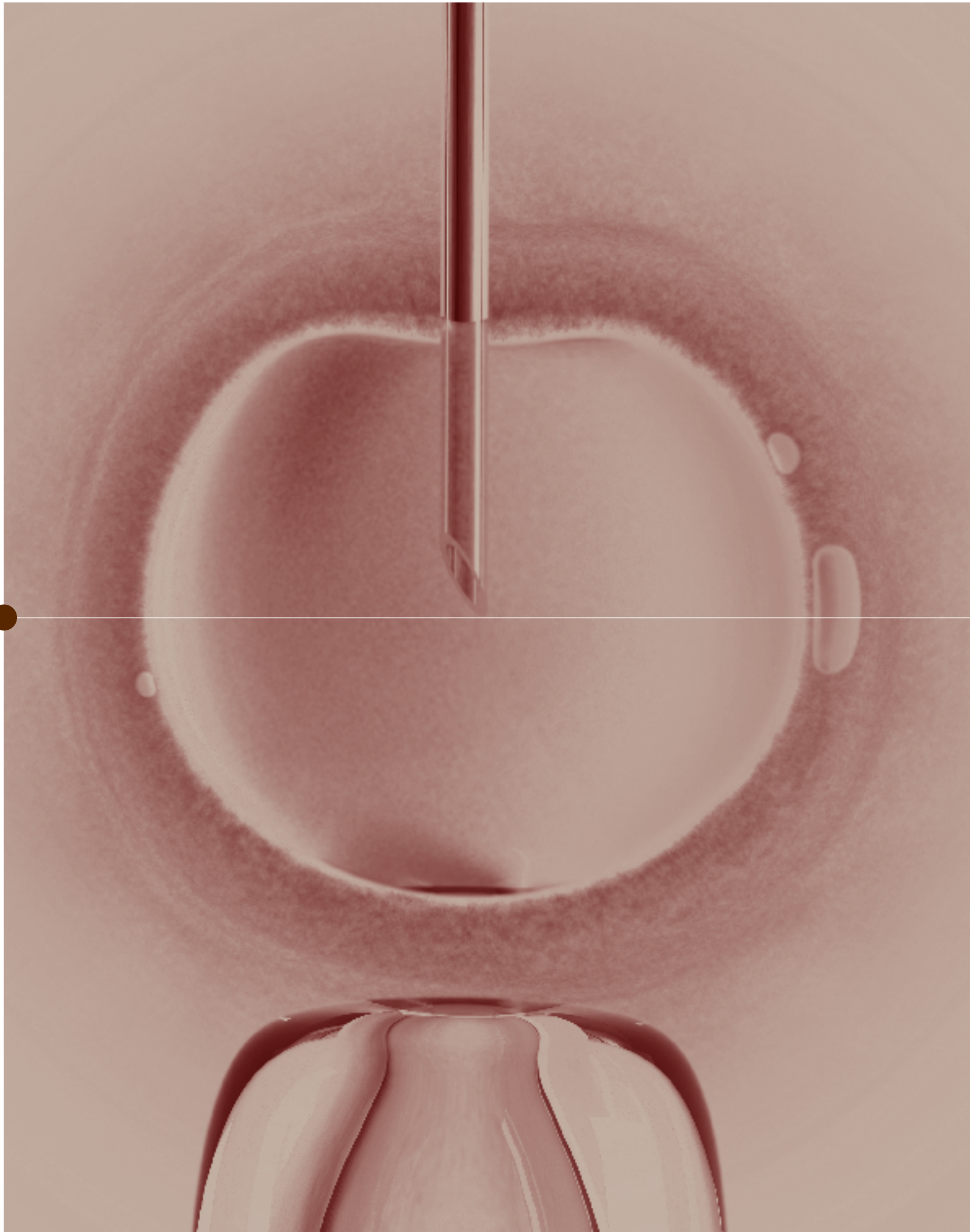
*Whereas the prohibition of surrogacy may encourage procreative tourism and thus increase the risk of exploitation of poor women abroad, the Commission contends, however, that this is not a sufficient reason to violate the value of human dignity upheld by Quebec society.*

*Further considering the risks to the autonomy, health and integrity of women, the physical and psychological risks for all actors involved, and considering that surrogacy is a form of instrumentalization and commercialization of the female body and of the human being, the Commission recommends:*

### Recommendation No. 10

That the Government of Quebec maintain the principle of the nullity of surrogacy contracts.

- 301 Procreative tourism towards Canada with a view to procuring donated gametes is negligible, on account of gamete scarcity. However, the legal vacuum surrounding surrogacy encourages Europeans to recruit surrogate mothers in Canada.
- 302 Two British students are said to have sold their eggs in the United States. They are said to have obtained \$6,000 and \$8,000 in lieu of the reimbursement of their expenses they would have obtained had they had remained in England. (Mike WENDLING, "British women sell eggs to US couples", *CNS News.com*, 26 November 2002, [online], <http://www.cnsnews.com/public/content/article.aspx?RsrcID=13227>).
- 303 J. COHEN, "Le tourisme procréatif: un pis-aller", *Gynécologie Obstétrique & Fertilité*, 2006, vol. 34, pp. 881-882.
- 304 Sam DOLNICK, "Les mères porteuses indiennes ont le vent en poupe", *Associated Press*, 30 December 2007 (our translation).





PREIMPLANTATION GENETIC DIAGNOSIS:  
MONITORING PRACTICE IN ORDER  
TO AVOID DRIFT

## PREIMPLANTATION GENETIC DIAGNOSIS: MONITORING PRACTICE IN ORDER TO AVOID DRIFT

For many years now, the development of obstetric knowledge and access to certain technologies have been helping people who need medical support to maximize their chances of having healthy children. For example, screening tests for certain diseases are carried out as part of the monitoring during pregnancy; maternal blood tests and ultrasound tests are also undertaken. Additional, more specific tests may be undertaken, such as determining the genetic profile of the fetus. All of these techniques make up what is called prenatal diagnosis\* (PND). More recently, a diagnostic method has been developed at a much earlier stage: preimplantation genetic diagnosis (PGD). It is only this latter method that the Commission is analysing in the current position statement on assisted procreation and the ethical issues it raises.

The initial objective of preimplantation genetic diagnosis is to propose an alternative to prenatal diagnosis, a technique achieved when the pregnancy is already underway. The results may lead parents to choose between termination or continuation of pregnancy if the fetus is a carrier of a disease or if it has one major malformation. As a result, some women may resort several times to abortion or have many miscarriages before having a viable baby.

In the context of *in vitro* fertilization, PGD makes it possible to avoid the passage through abortion, whether spontaneous or medical, because it occurs at the first stage of embryo

development, even before its implantation into the uterus. For people with no fertility problems, therefore, PGD requires mandatory treatments related to infertility that are invasive and costly. PGD is technically very complex,<sup>305</sup> and not only forces specialists into a race against time (they have only about 24 hours to perform the genetic test), but also requires that women are suitable for IVF, whose success rates vary between 13% and 28%.<sup>306</sup> Ultimately, the chances that a healthy embryo will develop and a child will be born are unfortunately quite low.

Specifically, PGD involves the genetic analysis of cells taken from an embryo derived from *in vitro* fertilization before its implantation in the uterus. With the development of knowledge on the human genome, the profile of people likely to use assisted procreation (AP) or diagnostic methods is expanding, and the nature of applications is also tending to diversify. Hence both of these diagnostic techniques – PND and PGD – have a potential for much wider uses than other techniques currently available.

PGD first appeared in the 1980s, but preimplantation genetic diagnoses were undertaken on a broader scale in the 1990s. In 2005 it was estimated that 7,000 PGD procedures were undertaken worldwide that enabled the birth of more than 1,000 healthy children.<sup>307</sup> The costs of PGD range between \$15,000 and \$100,000.<sup>308</sup> According to one hypothesis, the significant costs associated with PGD would seem to explain why PGD access is still limited today.<sup>309</sup> In Canada, PGD was performed in 27 IVF cycles in 2005. This resulted in six pregnancies and six live births, five singleton births and one birth of twins.<sup>310</sup> Even though PGD is available everywhere in the world, its practice is still fairly limited, however, according to a survey conducted in 2007 on behalf of the journal *Fertility & Sterility*: in the 54 countries surveyed, three countries banned it and only 34 resorted to it on a limited basis, often in a controlled and restrictive manner.<sup>311</sup>

In order to be able to identify the ethical issues posed by the development and use of PGD, it is important first of all to provide a summary portrait of its technical characteristics and main objectives. This review will help better understand the main reasons and medical indications that incite people to resort to this type of genetic analysis. The regulatory framework and the values underlying PGD will be presented later.

305 PGD requires *in vitro* fertilization even in cases where the couple is fertile. On this point see the section on egg donation in Chapter Two.

306 Z. PANDIAN *et al.*, “*In vitro* Fertilization for Unexplained Subfertility”, *Cochrane Database Systematic Reviews*, 18 April 2005, vol. 2.

307 J. COUSINEAU, *op. cit.*, p. 423.

308 To understand the significant difference in this estimate, something should be clarified. Performing PGD involves the use of a probe that allows the removal of cells from the embryo. However, diagnosing diseases such as Huntington’s disease requires development of a probe that can be used only in PGD for the purpose of identifying genetic markers for this specific disease. When a type of sensor already exists and is regularly used, the costs associated with research, development and commercialization of the innovation are amortized by the number of “clients” who have already undergone PGD of the same disease. However, when the type of probe corresponding to a disease does not exist, the production costs of the probe may be absorbed by the first “clients” using the probe.

309 Antoine ROBITAILLE, “Le cas du DPI”, *Forces: La voix internationale du Québec*, April 2003, p. 86.

310 Since PGD-related data were not directly requested in 2005, it is possible that PGD use is undervalued. (Joanne GUNBY, *op. cit.*).

311 “Chapter 14: Preimplantation genetic diagnosis”, *Fertility & Sterility*, April 2007, vol. 87, n°4, supplement 1, p. S49.

## THE TECHNIQUE: TWO MAIN OBJECTIVES

To obtain PGD, a woman must first submit to a process of *in vitro* fertilization and therefore of ovarian stimulation, whether she is fertile or not. Resorting to ovarian stimulation normally results in production of between ten and fifteen eggs. From these eggs, an average of five or six embryos are fertilized.<sup>312</sup> PGD is undertaken when the embryo has between six and eight cells, about three days after IVF. The biologist then performs a biopsy, that is to say, one or two cells are taken and subjected to genetic tests which can detect one or several genetic abnormalities being sought. In some countries it is common to carry out PGD for more than one abnormality, out of a possible 150.

At the present time, PGD is used to undertake two major types of genetic analysis:

- the karyotype, that is to say, the study of chromosomes. This procedure consists of a fluorescent *in situ* hybridization (FISH) in the interphase nucleus, which can detect abnormalities in the number of chromosomes or in their morphology, as in the case of trisomy 21 which has a third chromosome on pair 21. The karyotype also makes it possible to diagnose an abnormal number of chromosomes (also called aneuploidy\*) or (less frequently) a structural abnormality, and to identify the sex of the embryo (XX or XY).
- diagnosis of DNA molecules. This procedure consists of a polymerase chain reaction\* (PCR), and makes it possible to make “copies” of part of the DNA by multiplying it a million times or more. Diagnosis of DNA molecules using amplification is used for identifying monogenic inherited diseases.

The study of chromosomes can therefore identify numerical chromosomal abnormalities (an abnormal, excessive or insufficient number of chromosomes) or structural abnormalities (translocations, inversions). Numerical anomalies, or aneuploidy, are the most common type. They usually occur due to abnormal chromosome disjunction, which in most cases, leads to the arrest of embryonic development and spontaneous abortion in women. This is why, in the context of AP, it seemed natural to use PGD as a screening method to identify potential chromosomal aberrations, particularly in older women (between 35 and 40 years of age, depending on the centres), to verify the embryo’s “implantability” and thus improve the chances of successful IVF, given that risk increases with age.<sup>313</sup> While this indication remains the most common extension of preimplantation genetic testing to situations where, after the transfer of morphologically normal embryos, couples have nonetheless had repeated implantation failures or recurrent and unexplained abortions and such testing is more controversial.<sup>314</sup> Since PGD is a technique that risks damaging the embryo, the benefits sought (improving the chances of implantation) do not seem to outweigh the risks.

PGD can also make it possible to detect hereditary monogenic diseases. This category includes:

- Autosomal recessive\* diseases. Initially, PGD was developed for couples where both members were heterozygous\* and carried a recessive disease. The risk for them of transmitting the disease to their child is 25%. The carriers of such a disease are screened upon the birth of a sick child or on the basis of their respective family histories. Cystic fibrosis (mucoviscidosis) and spinal muscular atrophy\* are examples of autosomal recessive disease. These are serious, often fatal diseases, for which there is no treatment as yet.
- Autosomal dominant\* diseases. For a couple one of whose members is a carrier of an autosomal dominant disease, the risk of transmitting the mutation to the child is 50%, regardless of the sex of the child. The diseases in this category most frequently sought through PGD are Steinert's disease\* (or myotonic dystrophy\*) and Huntington's disease.<sup>315</sup>
- Recessive X-linked disorders\*. When men are carriers of a recessive disease located on chromosome X, they are necessarily affected by the disease since they have one X chromosome and one Y chromosome. When women are carriers of such a disease, the fact they have two X chromosomes means they carry the mutation but are not affected by the disease. They still run a 50% risk of transmitting it to their children; boys inheriting the mutation will get the disease but girls, like their mothers, will be healthy carriers of their mutation. In theory, men who suffer recessive X-linked diseases do not transmit the mutation to their daughters. However, as these men do not in general reach the age of reproduction, these diseases are generally transmitted by women. Duchenne muscular dystrophy\* and X-linked myotubular myopathy are examples of serious diseases in this category.

312 MCGILL REPRODUCTIVE CENTER, *Pre-implantation Genetic Diagnoses*, [online], <http://www.mcgillivf.com/e/McGillIVF.asp?page=184.190.189>.

313 Genetic screening of aneuploidy as well as PND makes it possible to detect specific aneuploidy syndromes: trisomy 13, 18 and 21, Klinefelter syndrome and Turner syndrome. Therefore, in association with the diagnosis of infertility, it is recommended for women who have reached a certain age: SOCIETY OF OBSTETRICIANS AND GYNECOLOGISTS OF CANADA, "Technical Update n° 232 of 23 August 2009, Preimplantation Genetic Testing", *Journal of Obstetric and Gynaecology Canada*, 2009, vol. 31, n° 8, p. 773. On the distinction between preimplantation genetic diagnosis and preimplantation genetic screening, see also COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *Diagnostic préimplantatoire II*, Position n° 14/2007, Berne, November 2007, p.12.

314 SOCIETY OF OBSTETRICIANS AND GYNECOLOGISTS OF CANADA, *op.cit.*, pp. 772-773. See also AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE, "Preimplantation Genetic Testing: a Practice Committee Opinion", *Fertility and Sterility*, 2008, vol. 90, Suppl. 3, pp. S141-142. Experts consulted by the Commission note, however, that if a young woman who suffered recurrent miscarriages which it is reasonable to believe were caused by the fetus suffering from aneuploidy, it would then be acceptable to conduct an PGD to evaluate the implantability of embryos.

315 COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *Diagnostic préimplantatoire*, Prise de position n° 10, Berne, 2005, p. 11.

A Quebec fertility centre states on its website that “[We] can do PGD for all single gene defects where the specific mutation is identified and as long as we can develop a special genetic probe for the disease”.<sup>316</sup> PGD can now also be used to screen for some mitochondrial diseases,<sup>317</sup> but the results of such screening remains uncertain.

To the knowledge of the Commission, although PGD services are available across Canada, only two laboratories in the country are able to undertake preimplantation genetic diagnosis *per se*. Biopsies are usually shipped to the United States for analysis. In Chicago, the Reproductive Genetics Institute would appear to be able to diagnose nearly a hundred apparently monogenic diseases.<sup>318</sup> The laboratory team also conducts tests for aneuploidy and chromosomal translocation\*.<sup>319</sup> As in most fertility centres around the world, the list of diseases that this laboratory team can diagnose is constantly evolving.<sup>320</sup>

After the karyotype or diagnosis of DNA molecules, the health professionals inform the couple or individual of the test results on the embryo the day of the test. They also state that PGD cannot be 100% reliable. In short, they inform their decision as much as possible about the number and selection of embryos to be transferred into the uterus of the mother. This transfer usually takes place on the fourth day of embryo development. However, it is possible that no embryo matches desired criteria and that none can be implemented as a result. The procedure can then be started over if the individual so wishes.

The two main techniques of genetic analysis described in this section (the karyotype and diagnosis of DNA molecules) make it possible to determine the presence of genetic mutations in order to avoid the birth of sick children. Yet it is important however to stress that PGD can also be used for additional or different reasons unrelated to the health of the hoped-for child. This theme will be discussed later in the section on the practice of this technique and the ethical issues it raises, after a brief description of the regulatory framework for PGD.

## THE REGULATORY FRAMEWORK<sup>321</sup>

In Quebec, under the new law on assisted procreation, PGD can only be performed in a centre for which a licence has been issued by the Minister of Health and Social Services, as is the case for all assisted procreation activities.<sup>322</sup> The conditions and standards for these activities are not yet known; they will be established by regulations in the near future, and it is reasonable to expect that the centres authorized to practice PGD will have to implement standard operating procedures.<sup>323</sup> For its part, the Canadian law on assisted reproduction does not expressly mention PGD, but it prohibits certain uses.<sup>324</sup> Specifically, sex selection for non-medical reasons is prohibited.<sup>325</sup> At the present time,<sup>326</sup> and subject to this prohibition, the recommendations of professional associations provide guidance to centres performing PGD.<sup>327</sup> Overall, these recommendations are a continuation of the conditions set by the legislator in countries where PGD is permitted or by authorities entrusted with oversight of assisted procreation.

- 316 MCGILL REPRODUCTIVE CENTER, *Pre-implantation Genetic Diagnoses*, *op. cit.*
- 317 Mitochondrial diseases are a group of inherited defects responsible for a lack of oxygen consumption and energy production. They can occur at any age and show very different symptoms. People suffering from these diseases are usually severely disabled and their life expectancy is limited. (Arnold MUNNICH, *Centre de référence des maladies mitochondriales*, [online], [http://www.aphp.fr/site/actualite/pop\\_centre9\\_2005.htm](http://www.aphp.fr/site/actualite/pop_centre9_2005.htm)).
- 318 The complete list is on their website: [http://www.reproductivegenetics.com/single\\_gene.html](http://www.reproductivegenetics.com/single_gene.html).
- 319 “Among chromosomal indications, reciprocal translocations account for half of PGD performed (40%)”. (Julie STEFFANN *et al.*, “Diagnostic prénatal et diagnostic pré-implantatoire: arbre décisionnel, nouvelles pratiques?”, *Médecine/Sciences*, November 2005, vol. 21, n°11, p. 989, [online], <http://ist.inserm.fr/BASIS/medsci/fqmb/medsci/DDD/8447.pdf>) (our translation).
- 320 “An ever longer list of diseases can be detected by PGD, while the advent of new technologies for genome amplification from single cells will help avoid the long and arduous development phase of diagnoses on isolated cells (...)” (*Id.*) (our translation).
- 321 From a document drafted by Marie-Pier BARBEAU, *L'apport d'un tiers au projet parental et le diagnostic préimplantatoire – Étude de droit comparé*, prepared for the Commission de l'éthique de la science et de la technologie, Québec, October 2008, pp. 11-14.
- 322 *An Act respecting clinical and research activities relating to assisted procreation*, *op.cit.*, articles 6, 7 and 15 to 24.
- 323 *Ibid.*, articles 30 and 31.
- 324 Erin L. NELSON, “Comparative Perspectives: Regulating Preimplantation Genetic Diagnosis in Canada and the United Kingdom”, *Fertility and Sterility*, 2006, vol. 85, pp. 1646-1651.
- 325 *Assisted Human Reproduction Act*, *op. cit.*, article 5(1) e) according to which, “no person shall knowingly [...] for the purpose of creating a human being, perform any procedure or provide, prescribe or administer anything that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an *in vitro* embryo, except to prevent, diagnose or treat a sex-linked disorder or disease.”
- 326 Namely in the absence of regulations concerning activities involving the alteration, manipulation, treatment or use of human embryos that are not prohibited by law (*Assisted Human Reproduction Act*, *op. cit.*, articles 10 to 13, 40 and 65) and subject to the decision of the Supreme Court on this law's constitutionality.
- 327 SOCIETY OF OBSTETRICIANS AND GYNECOLOGISTS OF CANADA, *op. cit.*, pp. 768-775.

The solutions are far from unanimous, however, and there are deep differences about the moral acceptability of PGD. “Several different positions for philosophical, socio-cultural or religious reasons can be identified,”<sup>328</sup> the International Bioethics Committee notes, referring to those who consider “that a human being, defined by some as a person, comes into existence at the time of fertilization [...] [and for whom] PGD is ethically unacceptable”; parallel to arguments “because it involves creating embryos for selection purposes,” some people evoke the spectre of eugenics\*, not to mention pressures that could be exerted on women. This is particularly true in countries such as Germany,<sup>329</sup> Austria,<sup>330</sup> Italy<sup>331</sup> and Switzerland,<sup>332</sup> where for all practical purposes PGD is prohibited, even if no law explicitly mentions it.<sup>333</sup>

For those who believe that “the full status of a human being is gradually acquired during intrauterine development” and who believe that “the well-being and health of the mother-to-be and the prevention of suffering of the future child justifies the procedure,” PGD is acceptable under certain conditions.<sup>334</sup>

- 328 INTERNATIONAL BIOETHICS COMMITTEE (IBC), *Report of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention*, Paris, 24 April 2003, UNESCO, paragraph n° 60 (our translation).
- 329 *Law on the protection of the embryo* (Gesetz zum Schutz von Embryonen-Embryonenschutzgesetz - EschG-, Law n° 745 of December 13, 1990). Although this law does not specifically deal with PGD, some of its provisions implicitly prohibit PGD. Firstly, because the law explicitly forbids the fertilization of an egg for a purpose other than obtaining a pregnancy [section 1 (1) 2]; it also penalizes any person who uses an embryo for a purpose other than ensuring its survival [section 2 (1)]; the embryo is itself defined as “a fertilized human egg that can grow as soon as the fusion of nuclei has taken place” and no distinction is drawn between the embryo and totipotent cells (that is, each cell capable of dividing and developing to produce all types of specialized cells) removed from the embryo [Section 8 (1)]; SÉNAT, *Le diagnostic préimplantatoire*, Les documents de travail du Sénat, Série législation comparée, n° L.C. 188, October 2008, p. 9. Since the adoption of the law, several bodies, including the National Council of Ethics (renamed the German Ethics Council in 2007), came out in favour of legalizing PGD subject however to very strict conditions. For an analysis of this question, see SÉNAT, *Le diagnostic préimplantatoire*, *op. cit.*, pp. 9-10, and Tanja KRONES, “The Scope of the Recent Bioethics Debate in Germany: Kant, Crisis, and No Confidence in Society”, *Cambridge Quarterly of Healthcare Ethics*, 2006, vol. 15, p. 274.
- 330 *Law n° 275 on Reproductive Medicine*, 1992, art. 9.1. Again, this prohibition is the subject of debate and several bodies have recommended lifting the ban: SÉNAT, *Le diagnostic préimplantatoire*, *op. cit.*, p. 11.
- 331 *Law n° 40 of February 19, 2004 on medically assisted procreation* (Nuove norme sulla procreazione assistita: vietata the fecondazione eterologa, Legge 19 febbraio 2004, n° 40, GU 24/02/2004), article 13 (3) b) prohibits embryo selection for the purposes of eugenics. Moreover, the law prohibits the cryopreservation and the destruction of embryos, which entails the obligation to transfer them all, including those with an abnormality (*id.*, art. 14 (2)). Also, as is the case with the German law, these provisions are subject to much criticism: SÉNAT, *Le diagnostic préimplantatoire*, *op.cit.*, p. 22; A. CONTI and P. DELBON, “Medically assisted procreation in Italy”, *Medicine and Law*, 2005, vol. 24, pp. 163-164; Paolo EMANUELE *et al.*, “Results of in vitro fertilisation in Italy after introduction of a new law”, *Fertility and Sterility*, 2007, vol. 1.
- 332 *Loi fédérale du 18 décembre 1998 sur la procréation médicalement assistée* (*Federal Law of 18 December 1998 on medically assisted procreation*), art. 5-3 which prohibits the removal and analysis of one or more cells from an *in vitro* embryo. However, while the law does not allow biopsy to be performed on the embryo, the analysis of polar bodies, that is to say, the analysis of impregnated ova before the fusion of maternal and paternal genetic material, is permitted. This technique can detect maternal abnormalities responsible for most cases of embryonic and fetal loss, but is limited in scope. (COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *Diagnostic préimplantatoire*, *op. cit.*, pp. 14-15; Herbert ZECH and Nicolas ZECH, “Controverses sur la procréation assistée en Europe”, *Forum médical Suisse*, 2 April 2004, n° 14, pp. 338, 340-341). For the arguments presented in favour of expanding access to PGD in this country, see also COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *Diagnostic préimplantatoire II*, *op. cit.* A bill expanding conditions of access to PGD should be tabled in Parliament in 2010: SÉNAT, *Le diagnostic préimplantatoire*, *op.cit.*, p.28.
- 333 The exception being, however, that analysis of polar bodies and cryopreservation of fertilized eggs before the union female and male pro- nuclei, in Germany as in Italy, and the example noted previously for Switzerland, are authorized by law (COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *Diagnostic préimplantatoire*, *op.cit.*, p. 29; John A. ROBERTSON, “Protecting embryos and burdening women: assisted reproduction in Italy”, *Human Reproduction*, 2004, vol. 19, pp. 1693-1695).
- 334 INTERNATIONAL BIOETHICS COMMITTEE (IBC), *op. cit.*, paragraph n° 60.

In most countries of the European Union<sup>335</sup> that have chosen to regulate PGD, its practice is in general limited to the detection of chromosomal abnormalities<sup>336</sup> and to cases where there is a risk of hereditary transmission of a severe early-onset genetic disease which is recognized as incurable at diagnosis. In such cases, “the family situation leads to the assumption that a significant risk exists for the embryo.”<sup>337</sup> Practice therefore covers all cases where “conventional” PND is performed, and should thus be based on medical reasons,<sup>338</sup> with the difference that the practice becomes an integral part of the act of procreation.<sup>339</sup> This is also why, as a way of avoiding drifts, some countries formally prohibit eugenic selection<sup>340</sup> and selection based on sex, unless medically indicated, i.e. in situations where there is a risk of transmission of sex-linked disease\*.<sup>341</sup> For its part, the United Kingdom has gone a step further, since the use of PGD for purposes of “family balancing”<sup>342</sup> is expressly prohibited by law. Other prohibited practices include selecting embryos carrying a disease or abnormality in preference to those without such a disease or abnormality (i.e. the voluntary promotion of the birth of disabled children).<sup>343</sup>

- 335 There is no single comprehensive European regulatory regime, so approval is therefore the responsibility of each State, subject however to its adhesion to the Oviedo Convention, article 14, which stipulates that “the use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child’s sex, except where serious hereditary sex-related disease is to be avoided” (COUNCIL OF EUROPE, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention of Human Rights and Biomedicine*, CETS n° 164, Oviedo, Council of Europe, 4 April 1997, came into force 1 December 1999).
- 336 This is the case notably in Belgium, where PGD is negatively defined and governed by an exception to set prohibitions (*Loi relative à la procréation médicalement assistée et à la destination des embryons surnuméraires et des gamètes*) (or *Law on medically assisted procreation and destination of supernumerary embryos and gametes*), C-2007/23090 of July 6, 2007, articles 67 and 68); Denmark (*Law of 2006 on artificial insemination [Bekendtgørelse af lov om kunstig befrugtning i forbindelse med behandling lægelig, Diagnostik og forskning mv, LBK nr 923 af 04 / 09 ]*, Ch. 2, art. 7.2: Mette HARTLEV, “Legislation and regulations in the Nordic countries. Is there a Nordic dimension?” in NORDEN, *PGD and Embryo Selection, Report from International Conference on Preimplantation Genetic Diagnosis and Embryo Selection*, Copenhagen, Nordic Council of Ministers, 2005, 111, p. 118); France (*Code de la santé publique* (or *Public Health Code*), articles L.2131 and L.2131-4-4-1); Spain (*Law of 1 June 2006 on the techniques of medically assisted reproduction [Ley 14/2006 sobre técnicas de reproducción humana asistida, BOE n. 126 of 27/5/2006, article 26.2 (c) (10)]*); Norway (*Law n° 100 of 5 December 2003 with respect to the medical uses of biotechnology*, article 2.14: Mette HARTLEV, *op. cit.*, p. 118); the Netherlands (*Law on the embryo of 2002*, which again does not explicitly govern PGD, but whose application regulations determine the conditions of implementation (*Regulations of 2003 respecting genetic tests and heredity counselling*)), SÉNAT, *Le diagnostic préimplantatoire, op.cit.*, pp. 23-24; Sweden (*Genetic Integrity Act*, Chapter 4, article 2: Ove HANSSON, “Three Bioethical Debates in Sweden”, *Cambridge Quarterly of Healthcare Ethics*, 2008, vol. 17, n° 3, p. 261); and the United Kingdom (*Human Fertilisation and Embryology Act 1990*, as amended in 2008 by the *Human Fertilisation and Embryology Act 2008* (c. 22), Schedule 2 (*Activities that may be licensed*), articles 1ZA(1) c), 1ZA(3) and 1ZB).
- 337 SÉNAT, *Le diagnostic préimplantatoire, op.cit.*, p. 7 (our translation).
- 338 INTERNATIONAL BIOETHICS COMMITTEE (IBC), *op. cit.*, p. 6.
- 339 *Ibid.*, p. 8.
- 340 This applies, among others, to Belgium: *Law on medically assisted procreation and destination of supernumerary embryos and gametes, op. cit.*, article 67, which refers on this point to the law of 11 May 2003 concerning research on *in vitro* (article 5, 4°).
- 341 *Ibid.*, article 67, 2°. This is also the case in most European countries that have legislated: Spain, Norway, the Netherlands (where the prohibition stems directly from the law), Sweden and the United Kingdom. See INTERNATIONAL BIOETHICS COMMITTEE (IBC), *op. cit.*, p. 8.
- 342 *Human Fertilisation and Embryology Act 1990*, as amended in 2008 (*Human Fertilisation and Embryology Act, 2008*), *op. cit.*, Schedule 2, article 1ZB (1). This does not mean that this practice is accepted in other countries, given the above-mentioned strict prohibition of choosing the sex for non-medical reasons. It should be noted that in Belgium, the Comité consultatif de bioéthique, or Bioethics Advisory Committee, made this point in a position statement taking three different positions: *Avis n°22 du 19 mai 2003 relatif au choix de sexe pour des raisons non médicales*. For a summary of various views expressed in this review, see Marie-Noëlle DERÈSE and Geoffrey WILLEMS, “La loi du 6 juillet 2007 relative à la procréation médicalement assistée et à la destination des embryons surnuméraires et des gamètes”, *Revue trimestrielle de droit familial*, 2008, vol. 279, pp. 343-344.
- 343 *Human Fertilisation and Embryology Act 1990*, as amended in 2008, *op. cit.*, article 13 (8) à (11).

But with the evolution of scientific knowledge in the medical field and related techniques, not to mention information available to patients nowadays, the understanding of the characteristics of gravity and incurability are also evolving; this understanding is becoming more subjective, more concerted and its evaluation from an objective point of view also varies over time.<sup>344</sup> This trend is also reflected in regulations, where there is a tendency to broaden the scope of PGD. Thus, in some countries, the detection of diseases whose hereditary transmission is not absolutely certain – for example, predisposition to certain forms of cancer – has become possible.<sup>345</sup> However, there is no list *per se* in the legislation of abnormalities whose diagnosis and screening are considered legitimate, but only indications of a general nature whose flexibility can justify such expanded uses.<sup>346</sup> The fact remains that, in general, “it is the institutions authorized to perform PGD or agencies authorizing them to do so that determine the cases where performing PGD is justified”<sup>347</sup> and in the event of a new indication, decisions will often be taken on a case by case basis.<sup>348</sup>

Furthermore, several countries have incorporated into their legislation a PGD application for medical reasons benefitting a third person (HLA\* or immunogenetic typing\*), an application most commonly referred to the practice known as “the double hope baby” or “designer baby\*”; this practice it should be remembered has not met with consensus. This practice was recently legalized in Belgium,<sup>349</sup> Denmark,<sup>350</sup> France,<sup>351</sup> Spain,<sup>352</sup> Norway,<sup>353</sup> Sweden<sup>354</sup> and the United Kingdom.<sup>355</sup> On the other hand, it is strictly prohibited in the Netherlands.<sup>356</sup>

- 344 For example, the Code of practice of the independent Agency mandated to regulate application of the law in the United Kingdom (Human Fertilisation and Embryology Authority (HSFA)) which states, in section 10.5 devoted to preimplantation diagnosis (*Embryo testing and sex selection*) dispose: (...) *When deciding if it is appropriate to provide PGD in particular cases, the seriousness of the condition in that case should be discussed between the people seeking treatment and the clinical team. The perception of the level of risk for those seeking treatment should also be an important factor for the centre to consider.* To this effect the following criteria should be taken into account (section 10.6): *the views of the people seeking treatment in relation to the condition to be avoided, including their previous reproductive experience; the likely degree of suffering associated with the condition; the availability of effective therapy, now and in the future; the speed of degeneration in progress disorders; the extend of any intellectual impairment; the social support available, and the family circumstances of the people seeking treatment* (HFEA, *Code of practice, op. cit.*).
- 345 SÉNAT, *Le diagnostic préimplantatoire, op. cit.*, pp. 17 and 26, which here cites the examples of Denmark and the United Kingdom.
- 346 This is especially true in the United Kingdom (*Human Fertilisation and Embryology Act 1990*, as amended in 2008 by the *Human Fertilisation and Embryology Act, 2008, op. cit.* (ch. 22), Schedule 2 (*Activities that may be licensed*), article 1ZA(2) in fine and in Norway (Mette HARTLEV, *op. cit.*, p. 118).
- 347 These agencies must however file reports in which they must in turn provide the consolidated list of diseases for which they have given permission.
- 348 For its part, the Agence de la biomédecine (Biomedicine Agency) in France has transitionally allowed the extension of PGD for detecting the most serious inherited forms of cancer, until such time as bioethics laws are amended. (AGENCE FRANÇAISE DE LA BIOMÉDECINE, CONSEIL D'ORIENTATION, *Délibération n° 2008-CO-12 du 28 mars 2008*).
- 349 *Loi relative à la procréation médicalement assistée et à la destination des embryons surnuméraires et des gamètes, op. cit.*, article 68 of which authorizes, in exceptional cases, the use of PGD in the interest of a child already born or of the authors of the parental project. It is up to the fertility centre to decide whether the parental project is being pursued solely in order to bring about this therapeutic benefit.
- 350 *Law on artificial insemination of 2006, op. cit.*, article 7.3, introduced in 2004 and which in each case involves a permit from the State Health Agency (Mette HARTLEV, *op. cit.*, p. 118).
- 351 Article 2131-4-1 of the Code de la santé publique, introduced in 2004, under which diagnosis can be authorized on a trial basis and is presented here again as an exception. This authorization is itself subject to the issuance of a permit by the Agence de la biomédecine.
- 352 *Law of 1 June 2006 on the techniques of medically assisted reproduction, op. cit.*, art. 12.2 (2). An express authorization must be obtained from the autonomous region, after receiving a favorable opinion from the National Commission for Assisted Reproduction (SÉNAT, *Le diagnostic préimplantatoire, op.cit.*, p. 20).
- 353 *Law n°100 of 5 December 2003 with respect to the medical uses of biotechnology, art. 2.14* (Mette HARTLEV, *op. cit.*, p. 118).
- 354 *Genetic Integrity Act*, chapter 4, art. 2 (Sven Ove HANSSON, *op. cit.*, p. 262).
- 355 *Human Fertilisation and Embryology Act, 1990*, as amended in 2008 (*Human Fertilisation and Embryology Act, 2008*), *op. cit.*, (ch. 22), Schedule 2, article 1AZA (1 d)).
- 356 Not under the law, but under *Regulations of 2003 respecting genetic tests and heredity counselling* (SÉNAT, *Le diagnostic préimplantatoire, op. cit.*, p. 23).

A greater number of European countries have legislated on PGD, but countries on several other continents have also legislated in this area. The practice is subject to regulations for example in New Zealand<sup>357</sup> and also in federated States such as Australia, such as in the State of Victoria.<sup>358</sup> This is not the case in the United States, however, where the main centres performing PGD are private, and in the absence of federal<sup>359</sup> or state<sup>360</sup> legislation in this area, “have a considerable freedom in deciding about the indications and methodologies of PGD.”<sup>361</sup> On the other hand, professional associations such as the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) have extremely strict membership requirements, and have developed guidelines for their members. As it stands, ASRM’s guidelines govern the practice of PGD and mainly concern clinical applications of PGD. This association endorses neither sex selection for reasons of convenience<sup>362</sup> nor genetic testing<sup>363</sup> for the purpose of increasing the success rate of IVF, and which it does not recommend, given the results obtained.

The PGD regulatory framework is thus derived from many sources. In North America, it involves more self-regulation, whereas in Europe there is a greater tendency to establish a legislative or regulatory environment. While there are many different positions regarding the legitimacy of PGD, there is nevertheless consensus about limiting the practice to medical indications. These indications are however subject to different interpretations in each country, which leads to the conclusion that there is a plurality of positions on PGD.

## GENERAL REFLECTIONS ON THE USE OF PREIMPLANTATION GENETIC DIAGNOSIS

Preimplantation genetic diagnosis now offers applications that generate debate. From an ethical perspective, PGD involves the *in vitro* creation and selection of embryos on the basis of certain genetic characteristics, and for this reason, 10 years after the advent of PGD, it is still provoking conflicting positions. For some people, any use of PGD can be ethically justified in terms of the reproductive autonomy of individuals and protection of the child's welfare not to the mention that of the community, especially when genetic diagnosis aims to avoid the suffering and costs related to certain genetic diseases or abnormalities. For others, PGD and the selection of genetic traits are unacceptable, whatever the reason invoked, since genetic selection is related to the quest of the perfect baby and to a liberal form of eugenics. Both positions are extreme, however, and most views are situated in an intermediate zone where the acceptability of PGD use is determined based on the context and the nature of the reasons motivating such use.

Whatever form PGD takes, whatever indications are invoked, ethical reflection on the subject may take different approaches. In line with the analytical framework the Commission adopted in preparing its position statements, it bases its thinking on a value-centred approach. After some general remarks about some contextual elements and some implications stemming from development of PGD supply, an analysis will be presented of key values that may be involved in decisions concerning the selection of embryos, in order to highlight the ethical issues this practice puts at stake.

- 357 A country where the tissue typing\* (HLA typing) is also permitted, and where, as in most countries that have legalized it, such typing is evaluated on a case by case (HEALTH CANADA, ASSISTED HUMAN REPRODUCTION IMPLEMENTATION OFFICE, *Issues related to the regulation of pre-implantation genetic diagnosis under the Assisted Human Reproduction Act*, 2005, p. 4).
- 358 Where the Infertility Treatment Authority responsible for implementing and overseeing the law publishes the list of diseases for which PGD is allowed (HEALTH CANADA, *op.cit.*, p. 3).
- 359 Apart from the *Fertility Clinic Success Rate and Certification Act* passed in 1992 (Pub. L. No. 102-493, 42 USCA & 201, 263 (a) (1-7)) commonly called "the Wyden Law", the application of which falls under the responsibility of the Center for Disease Control (CDC), there is no national law on assisted procreation. The federal government's oversight role is limited to collecting data on success rates of fertility clinics and to listing clinics which have not filed annual reports. (David ADAMSON, "Regulation of Assisted Reproductive Technologies in the United States", *Family Law Quarterly*, 2005-2006, vol. 39, n° 3, p. 727).
- 360 Member states could eventually legislate on any issue, but for now, to the Commission's knowledge, none of them has adopted specific legislation on the subject. However, a number of states, including the State of New York, have adopted provisions concerning standards which these institutions must meet to be allowed to perform techniques such as PGD: NY Pub. health & 570-581 (2005); NY Comp. Codes R. & Regs.Tit. 10 & 58 (2005).
- 361 INTERNATIONAL BIOETHICS COMMITTEE (IBC), *op. cit.*, paragraph 41 (our translation). But a number of regulations adopted by the Food and Drug Administration (FDA) are still applicable – they concern the organization, handling safety and training for staff working in their laboratories. (David ADAMSON, *op. cit.*, pp. 725 and 729).
- 362 AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE, "Sex Selection and Preimplantation Diagnosis, Ethics Committee Report", *Fertility and Sterility*, 1999, vol. 72, n° 4, pp. 595-598. These recommendations were revised in 2006 and the association has not changed its position.
- 363 AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE, "Preimplantation Genetic Testing: a Practice Committee Opinion", *op. cit.*

## The change in the meaning of assisted procreation

Originally, PGD was developed because it could help avoid the use of PND. By choosing an embryo that did not carry a genetic mutation even before it was implanted into the mother's uterus, diagnosis of a fetus was avoided, as well as the need to take a decision whether to continue with pregnancy or not, in the event of a positive result:

« The main advantage of PGD is that it avoids MIP [medical interruption of pregnancy], after trophoblast biopsy or amniocentesis, which are always painful experiences for couples and especially for the mother. It will therefore concern couples at risk of transmitting a genetic disease, who already have a child with the disease, who are well acquainted with the consequences of the disease and who do not wish to use conventional PND for different reasons.<sup>364</sup>



It should be remembered that assisted reproductive technologies were developed to overcome infertility problems in heterosexual couples or to respond to the desire for children of single, menopausal or homosexual individuals. Since it cannot be performed in the absence of IVF treatment, preimplantation genetic diagnosis is now expanding the access to AP techniques, not only to people who need medical assistance to conceive, but also to single people or couples, whether fertile or infertile, who want the benefit of such a diagnosis for embryo selection (whether because they know they are at risk of transmitting a genetic disease, or because they have a seriously ill child, etc.).

This broadening of the reasons justifying access to assisted procreation is somehow changing the meaning of AP, which is now becoming seen not just as a way to overcome problems of natural conception so that people can have a child related to them biologically, but also as a way for fertile or infertile people to select an embryo that will become a *healthy* child or, where appropriate and depending on certain indications, a child with genetic characteristics sought by its future parents (such as immunogenetic compatibility\* or gender preference).

Other AP techniques raise the question of knowing how far it is acceptable to go, in meeting the desire for a biological child. However, it should also be foreseen that the development of PGD will raise the question of how far it is acceptable to, in meeting the desire for a *healthy* biological child or one with specific genetic characteristics. Assisted procreation, including PGD, highlights more clearly the issue of limiting indications for embryo selection, and this is because of a single presupposition: for people undergoing PGD the procedure seems less painful, from an external point of view, than PND, which may raise the possibility of abortion in the event of positive diagnosis. This presupposition is based mainly on the availability of, and ease of access to, AP, which seems likely in coming years, but it also conceals the complexity of the IVF procedure, as well as the risks and negative consequences it sometimes involves for the unborn child and for people undergoing the procedure.

## The complexity and risks of the procedure

An analysis of issues related to PGD must take into account the complexity and the risk associated not only with PGD itself, but also with the related procedure of IVF. It should be noted that in psychological terms, resorting to PGD may provide some people with relief. Indeed, gaining the chance of not transmitting a hereditary disease may constitute a noticeable benefit. PGD is often presented in certain contexts as an alternative to PND, yet it is not a harmless solution. Resorting to PGD involves physical and psychological constraints that pose risks to all those involved.

For the embryo, the removal of cells as part of the diagnostic technique involves some risk for gestational development as well as development of the child at a later date. For women, the main constraints are related to IVF procedures. To have a significant number of embryos at one's disposal requires first of all an increase in oocyte production through ovarian stimulation. This procedure always involves a number of risks, but the risks of hyperstimulation seem greater when a fertile woman undergoes the procedure.<sup>365</sup> For couples or single women, the complexity of the procedure leading to PGD is often mentioned.<sup>366</sup> These people experience a difficult period of uncertainty, since they cannot ignore the risks of failure of IVF, of misdiagnosis or the lack of an embryo with the desired genetic characteristics. All the decisions they have to take as part of the IVF process are based on sometimes painful choices that are experienced with apprehension, whether the choice is to undertake a procedure or not, to react to diagnosis (to implant an embryo or not, to accept genetic characteristics or not), or to submit to a new IVF cycle, or not, after implantation failure. In addition, pregnancy itself is more medicalized in this context and can be experienced as a difficult period.

364 INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE (INSERM), *Tests génétiques - Questions scientifiques, médicales et sociétales*, Paris, 2009, p. XXIX (our translation).

365 COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ (CCNE), *Avis n°72 Réflexions sur l'extension du diagnostic préimplantatoire*, 4 July 2002, p. 6. According to some studies in France, the majority of couples who requested PGD were fertile. Moreover, two experts making presentations during the hearings of the Commission de l'éthique de la science et de la technologie maintained that a very large proportion of people seeking PGD are fertile couples who are already parents of seriously ill children or who have already had a pregnancy terminated after a positive PND.

366 This idea was repeatedly heard during the public hearings conducted in autumn 2008. Representatives of infertile couples, genetic counsellors, an anthropologist and a geneticist gave evidence of the tensions experienced by couples involved in such a procedure.

The medical team may experience significant psychological and clinical problems, when they are aware of the tensions felt by the couple or single person, and those around the decision-making process. The medical team is mindful of the hopes nurtured by people ready to undergo an IVF and PGD procedure in order to have a biologically related and healthy child, and the team may feel responsible for achieving this important goal. Moreover, without clear guidelines regarding indications and acceptable practices, several professional teams experience some discomfort about unusual requests. These teams are anxious to meet the freely expressed desires of individuals, but they say they are concerned about the “social” implications some decisions may have. In the absence of professional guidelines and precise decision algorithms for PGD access and indications, some professional teams experience the same discomfort each time they face unusual requests.

Another point worth noting in this respect is that the likeliest outcome of PGD is multiple pregnancy and multiple births. Indeed, since women who want to undergo PGD first have to undergo IVF, more than one embryo will normally be implanted into the uterus.<sup>367</sup> All the risks and disadvantages PGD poses for the embryo, and the various constraints it imposes on the woman, the couple and the medical team, make it hard to consider PGD as an accessible solution whose consequences are easy to live with. Especially since some medical *constraints* aim primarily to treat infertility; this is not the case for a woman who does not need to resort to AP techniques to achieve a parental project but must undergo ovarian stimulation and the inconvenience of an IVF cycle so that genetic diagnosis of embryos can be performed.

### **Innovative character and risk assessment**

While the constraints induced by PGD can be identified, it must however be noted that the direct (physical or psychological) consequences flowing from this procedure are hard to assess accurately. To date, not enough PGD procedures have been undertaken to allow a good grasp of all the ins and outs of PGD, a solid understanding of the risks involved and any certainty whether the procedure will work or not. The lack of perspective and of rigorous long-term studies related to this diagnostic technique in humans is also the main justification invoked in some countries for its prohibition: “the long-term consequences for the embryo examined are not known; diagnostic errors are always possible.”<sup>368</sup>

The Commission therefore considers that the innovative character of PGD should be clearly explained to those opting for it, including the fate of surplus embryos. Indeed, it happens that the IVF technique will create several embryos free of the genetic disease to be avoided, with the result that supernumerary embryos may not be used for immediate reproductive purposes. Faced with this situation, choices must be made by the individuals who own the embryos, whether to cryopreserve them for future use, to donate them to research or to destroy them. Since the effects of PGD on an embryo which is then subjected to cryopreservation are not yet known, those responsible for the decision should be informed about the innovative character of these techniques and about attendant risks.<sup>369</sup>

The success of PGD is not guaranteed and medical errors may occur, particularly given the laboratory technique (PCR) and the limited time available for analysis: “[...] the brief period of diagnosis (12 to 24 hours) imposed by the need for rapid transfer of embryos requires the use of analytical techniques that are also rapid.”<sup>370</sup> Such errors have occurred in most centres performing PGD around the world.<sup>371</sup> These errors can occur for various reasons, for example when diagnosis has unfortunately focuses on one or several healthy cells, whereas other cells presented genetic abnormalities or vice versa.<sup>372</sup> Moreover, it is not possible to diagnose all mutations which may be present during a single PGD procedure. An embryo could thus not be a carrier of a certain disease but could suffer from another health problem:

« Specialists do nothing but evaluate the morphology of certain chromosomes, time here acting as the most important limiting factor. In practice, what chromosomes “should we look for?” “We arbitrarily chose the ones that seem to involve the greatest risk of miscarriage or trisomy. In practice, chromosomes 13, 18 and 21 for trisomy, 16 and 22 for miscarriages,” says Professor Libaers [of the clinic at the Free University of Brussels (VUB)]. Particularly in this case, prior discussion with couples should be thorough.<sup>373</sup> »

In addition, in the light of current research, it is not yet possible to determine whether the samples taken from the embryo during the PGD procedure can affect the fetus or child at a later date.<sup>374</sup> As a result, the medical team is accustomed to recommend to parents that they inform their pediatrician about the situation, so this latter can monitor the child. As one geneticist noted at hearings held by the Commission, “the risks to children are not rigorously demonstrated, yet it turns out that diagnostic errors can occur and these experiences are never happy ones for parents.”

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- 367 Data about the risk of multiple pregnancy following PGD, such as date on IVF without PGD, vary widely. In 2000, the European Society of Human Reproduction and Embryology (ESHRE) reported that of approximately 123 births obtained after PGD (all indications), 31% were multiple pregnancies (37 twins and 3 triplets). For the same year, another centre reported a rate of 9% of twin births, 7% of triplets and one case of five fetuses all of which miscarried. (C. STROM *et al.*, “Neonatal outcome of preimplantation genetic diagnosis by polar body removal: the first 109 infants”, *Pediatrics*, October 2000, vol. 106, n° 4, p. 652).
  - 368 COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *op. cit.*, p. 40.
  - 369 The McGill Centre's information document notes that since there have not been many births of embryos previously biopsied and cryopreserved (i.e. that underwent PGD before being cryopreserved), “the prognosis from these cases is poor.” (MCGILL REPRODUCTIVE CENTRE, *Pre-implantation Genetic Diagnoses*, *op. cit.*).
  - 370 Julie STEFFANN *et al.*, *op. cit.*, pp. 990-991 (our translation). See also COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *op. cit.*, p. 16.
  - 371 S. LAVERY, “Preimplantation genetic diagnosis and the welfare of the child”, *Human Fertility*, 2004, vol. 7, n° 4, p. 297.
  - 372 COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *op. cit.*, pp. 19-20.
  - 373 Jacques PONCIN, “Le DPI... ou choisir l'enfant à naître?”, *L'Observatoire de la génétique*, mai 2002, n° 3, [online], [http://www.ircm.qc.ca/bioethique/obsgenetique/zoom/zoom\\_02/z\\_no3\\_02/z\\_no3\\_02\\_2.html](http://www.ircm.qc.ca/bioethique/obsgenetique/zoom/zoom_02/z_no3_02/z_no3_02_2.html) (our translation).
  - 374 Sonja DESMYTTERE *et al.*, “Two-year auxological and medical outcome of singletons born after embryo biopsy applied in preimplantation genetic diagnosis or preimplantation genetic screening”, *Human Reproduction*, 2009, vol. 24, n° 2, pp. 470-476.

For all these reasons, many clinics recommend that their clients also seek prenatal diagnosis<sup>375</sup> to confirm the outcome of PGD. It should be borne in mind that the practice of PND poses additional risks for the fetus and that it does not avoid the risk of miscarriage. Parents should definitely be made to understand that PGD does not provide an absolute guarantee against the future development of disease: it is impossible to look for everything, and only things one looks for can actually be found.<sup>376</sup> It should also be noted that the results obtained during PGD can vary significantly depending on the competence of professionals performing the analysis, as is the case with most medical techniques.

The decision whether or not to proceed with PGD should balance the severity and frequency of risk with the benefits of preimplantation embryo selection. Given the success obtained with this technique, namely the birth of healthy children biologically related to their parents, it can still be difficult for a medical team, when facing problematic medical or psychological situations, to justify refusing PGD to people who are informed about its technical limitations, potential risks and complex processes, but who still insist on using it. Nevertheless, it is important that sufficient and adequate counselling be provided to them. In addition, it is essential that the information they are given is designed to enable them to make a free and fully informed choice,<sup>377</sup> whatever the circumstances, but even more so where the health of the child is the primary objective. Moreover, they should also be informed about other available opportunities:

- Conceiving with IVF and requesting PGD;
- Conceived with IVF and seeking donated gametes;
- Conceiving naturally and requesting PND;
- Conceiving naturally and hoping the child is healthy;
- Adopting a healthy child;
- Renouncing to the parental project.

This brief overview shows that it is hard to make a fair assessment of the balance between risks and benefits at the present time. Like many other assisted procreation practices, PGD is still considered a technological innovation, although the results of tests on animals have led to its application in humans. Thus, while acknowledging the importance of technological innovation in health, some instances such as the Court of Cassation in France, however, take a more nuanced position on the subject, this latter Court holding that “these risks generate a duty of prudence with respect to scientific uncertainties and refer to the precautionary principle [...]”<sup>378</sup>

*Whereas limited research has been undertaken on long-term monitoring of the health status of children resulting from assisted procreation who have also undergone PGD during the embryonic stage, as well as the innovative character of PGD, the Commission recommends:*

#### Recommendation No. 11

- That the Minister of Health and Social Services establish a specific licensing mechanism for approval of centres performing PGD;
- That the Fonds de recherche en santé du Québec (FRSQ) set up a research program for evaluating the risks of PGD for embryos and children resulting from this procedure.

375 S. LAVERY, *op. cit.* Moreover, the study *L'expérience parisienne du diagnostic génétique pré-implantatoire: bilan des premières naissances* noted that “cord blood was routinely removed at birth to confirm PGD.” (N. FRYDMAN *et al.*, “L'expérience parisienne du diagnostic génétique pré-implantatoire (DPI): bilan des premières naissances”, *Annales d'endocrinologie*, 2005, vol. 66, n°3, p. 299) (our translation).

376 Jacques PONCIN, *op. cit.*

377 COUR DE CASSATION, *L'innovation technologique – Rapport annuel 2005*, Paris, 2006, p. 122, [online], [http://www.courdecassation.fr/IMG/pdf/cour\\_cassation-rapport\\_2005-3.pdf](http://www.courdecassation.fr/IMG/pdf/cour_cassation-rapport_2005-3.pdf).

378 *Ibid.*, p. 121 (our translation).

## THE VALUES AT ISSUE IN PREIMPLANTATION GENETIC DIAGNOSIS

The values that particularly concern the Commission de l'éthique de la science et de la technologie in its reflection on preimplantation genetic diagnosis are the health and well-being of children resulting from PGD, the dignity of these children, the reproductive autonomy of persons and the equality of all human beings. After a brief overview of general issues raised by the use of PGD in relation to these core values, PGD will be addressed more specifically depending on the purposes underlying its use, and recommendations will then be made.

### The health and well-being of the child

The context of AP is distinct from other clinical care contexts, particularly given the rapid development of this set of practices in the private sector and its innovative character. These medical practices have been developed to meet the unfulfilled desire for a child, for physiological, personal or social reasons (in the case of single, menopausal or homosexual individuals). Beyond these considerations, what clearly distinguishes assisted procreation, in ethical terms, from other medical practices is its outcome:<sup>379</sup> the “therapeutic” techniques involved in AP lead to the birth of a human being.

Although the protection or the need to “take into consideration” the welfare of the child seems to be at the heart of ethical arguments and texts framing preimplantation genetic diagnosis in several countries, this value is subject to different interpretations. Accordingly, the welfare of the child can be understood minimally as one involving rigorous medical responsibility for the safety of diagnostic techniques and for physical risks faced by children resulting from PGD.

For its part, the Commission considers that this value is related to a responsibility borne by all actors involved in decision-making about PGD, to ensure that the child resulting from it has the same chances as children conceived naturally with respect to its physical and psychological development.

In this sense, the Commission is concerned about the negative consequences of a birth attended by a serious disabling illness, for which no treatment is available and that will seriously jeopardize the quality of life of the child. However, promoting health and well-being does not amount to selecting the most genetically perfect or the highest-performance children. In some cases, promoting the overall health and welfare of the child may take the form of according particular attention to it and may manifest itself in parents exerting pressure on it. Indeed, a child selected *for* its genetic characteristics – making it likely to meet hoped-for social “norms”, to attain a higher level of performance, to achieve professional success, for example – could, without the parents necessarily being aware of it, become “responsible” for being and becoming what its parents hoped for. Promoting the welfare of the child therefore means taking into account the physical and psychological health of the child resulting from PGD. However, in the view of the Commission, this welfare also means that the child should be allowed to be born in a context that, emotionally, will be most conducive to its harmonious overall development.

## The dignity of the child

The dignity of the child relates back to two principles underlying this value and which the Commission would like to define, since they arise in some clinical situations, the most often with respect to requests of people who want a preimplantation genetic diagnosis.

### The non-instrumentalization of the human being

The Commission endorses the principle that the human being should be an end in itself and should never be considered *solely* as a means serving the end pursued by someone else. In other words, the person should never be perceived solely as the means of attaining an objective, but always as an end in itself. In terms of PGD, the non-instrumentalization of the human being is most often invoked in proposing that embryo selection not be viewed primarily as a means of meeting particular needs. The PGD application that seems to pose the greatest threat to respect for the singularity of each human being is when it is performed in order to select an embryo that has a compatibility enabling it to be a donor, usually for an already specified purpose. In this situation, the child is born *because* it is compatible, and it is selected *in order* to be a donor.

### Respect for symbolic freedom

The symbolic freedom of a being refers to the lack of predetermination in the direction the life project of each human being takes. In the case of PGD aimed at the health of the child, it is not clear that the symbolic freedom of the child is endangered, as such, although the argument of the slippery slope underscores the deterministic potential caused by advances in human genetics:

« Insofar as embryo selection is inherent to IVF, one wonders if it becomes wrong simply because it is often guided by the search for accurate information on a particular characteristic of the embryos, assuming that the intended purpose is admissible. If no choice is made, then things are left to chance. But in what sense would leaving things to chance be more moral than a deliberate choice? [...] The child will in any case be a singular being and it is this singularity that the human being unique; the biological link, in passing to the foreground, does not mitigate this in any way.<sup>380</sup>



379 It should be remembered, however, that at the end of life, other “therapeutic techniques” also raise significant ethical issues when their finality is the death of a human being. This subject is poles apart from the subject of the present position statement of the Commission.

380 CCNE, *Avis n°72 Réflexions sur l’extension du diagnostic préimplantatoire*, op. cit., p. 6 (our translation).

In the case of diagnosis for the voluntary birth of a child with a disability, it is clear that the child will have to assume a decision taken by its parents and the possibly serious consequences stemming from this decision. Once the child becomes an adolescent and is old enough to question the parental decision, it will then be in a unique position:

« This adolescent will always be in an asymmetrical position relative to its parent. But democracy requires that we all be in the same position, which each of us must reappropriate starting at adolescence. But in constructing ourselves, we cannot deny genetically transmitted elements in the same way as we would information received sociologically. It therefore seems doomed forever to remain “the child of its parents”, their “creature”... Each person’s contingent quality of being natural is thus denied, which each person can reappropriate precisely because it is contingent (this is not at all a reference to a human nature). The challenge is thus to preserve the conditions of human possibility for each person, which requires that each person be free to exist in its own right, and that humanity could eventually freely destroy...<sup>381</sup>



The fundamental issue where the symbolic value of freedom is concerned appears to be neither the merits of the family decision, nor the love that will be shown towards the child. The issue appears to be more on the symbolic level, in the intrinsic quality of the human being, free from predetermination in the direction its life project will take. The risk of eugenic drifts or of limiting the symbolic freedom of beings resulting from PGD is cause for concern, especially given the development and improvement of diagnostic practice. Indeed, while the great advantage of PGD lies in its being performed at an early stage, it also raises many ethical questions. If it is not properly supervised, then PGD could “lead to a considerable expansion of all kinds of screening tests made possible by nanotechnologies and biochips.”<sup>382</sup> Without falling into fanciful predictions, it is conceivable that the identification of new genes would incite prospective parents to seek embryo selection, based on genetic discoveries and according to subjective preferences, which could be influenced, possibly in an insidious fashion, by a kind of social norm.

## Reproductive autonomy

The value of reproductive autonomy of individuals and couples was noted above. This kind of autonomy is defined as the ability of an individual or couple to decide whether to reproduce or not and whether to resort or not to various available means in fulfilment of a parental project. The individual's freedom of choice is a fundamental value in modern societies and it is indisputably recognized to include the private character of the decision to have a child, and when. The development of diagnostic techniques and expanded indications of preimplantation genetic diagnosis raise questions, however, about whether the free choice of individuals is respected in all situations. Indeed, it seems that certain parental requests are challenged by values such as respect for the dignity of the child and protection of its welfare and respect for equality among people. These situations create real value conflicts.

In the context where the objective of avoiding the birth of a seriously ill child motivates the use of *in vitro* fertilization and preimplantation genetic diagnosis, the decision to use diagnostic techniques such as prenatal diagnosis is now considered a legitimate exercise of the reproductive autonomy of individuals. The same applies to using PGD for the same purpose. In terms of reproductive autonomy, PGD challenges the scope of that value and poses an ethical issue: how far should we go in recognizing the private nature of the decision of couples or individuals to resort to embryo selection on the basis of genetic analysis? Should the severity of disease be defined only by couples? Is reproductive autonomy unlimited? If reproductive autonomy has limits, what are they and how can they be justified ethically?

In general, the individual's autonomy encounters a limit at the point where it threatens to impede the autonomy of another individual or to go against the collective interest. In the context of reproductive health, private decisions reach a limit when they are likely to hinder the autonomy of an individual intimately involved in the situation: the child. On the one hand, if scientific evidence established that the PGD technique *per se* constituted a serious risk to embryo or child development, it seems clear that the freedom of couples to use it could not be exercised, since it would constitute a direct threat to a third person. On the other hand, the reproductive autonomy of couples could also threaten the autonomy of the child in cases where the requests they articulated resulted in a child's disability (in the case where PGD sought the deliberate birth of a child with a disability).

- 381 Christian BOUCHINDHOMME, "Légiférer par anticipation? La démocratie face aux avancées des sciences de la vie; présentation de la position de Jürgen Habermas, à partir de son ouvrage, *L'avenir de la nature humaine. Vers un eugénisme libéral?* ", Lecture given on 29 January 2003 (our translation).
- 382 E. AZARIA and G. GRANGÉ, "Diagnostic préimplantatoire: considérations d'ordre éthique", *Gynécologie Obstétrique & Fertilité*, June 2007, vol. 35, n° 6, p. 505 (our translation).

The physiological risks arising from PGD for women are not different from those arising from IVF. On the other hand, PGD poses non-negligible psychological and emotional risks in the event of failure or misdiagnosis, where the health of the child is the object. These risks highlight what is necessarily involved in the exercise of genuine autonomy. Indeed, for a decision to be truly autonomous, it should have two important characteristics: it should be free and informed. Taking autonomous decisions does not just mean taking decisions for oneself. It also means being able to assume this role, being capable of and equipped for the exercise of decision-making. Given the opportunities and risks posed by PGD, promoting the reproductive autonomy of couples comes with a significant requirement: it requires that the procedure be based on a free and informed decision.

A couple or single woman freely takes a decision when that freedom is exercised without any bias, undue influence of any (psychological, emotional, social or professional) pressure. For consent to be valid, people should indeed be able to judge the situation. In addition, it is important that the financial interests potentially pursued by some fertility centres have absolutely no impact on their decision. The decision is also informed when a couple or a single woman has relevant and sufficient information to evaluate the benefits and risks underlying the technique.

Although people applying for PGD are physically and mentally healthy and capable of making rational decisions, they are nonetheless subject to some form of vulnerability. Several authors point out in this connection that the limits of their own scientific knowledge place all patients in a vulnerable position.<sup>383</sup> This implies that particular attention should be paid to the quality of the consent of a couple or a single woman gives, when initiating a procedure involving PGD and that this quality is assessed according to the requirements of a free and informed decision.

This goal is not easy to achieve. Indeed, in cases where a couple or single woman sees PGD as a last resort, the ultimate hope, clinicians and psychologists attending to them may ask themselves whether the decision is truly of a free nature. Are these people freely assuming risks and the uncertainty of results obtained through the IVF and PGD procedure? Are they committing to PGD freely of any psychological and emotional pressure, or are they doing so because they see no alternative? Professionals monitoring such requests have the responsibility to assess to what extent the desperate character of certain situations may compromise the judgment of applicants.

## Equality among people

Respect for human dignity requires that equality among all people be recognized. All human beings are born equal, and this fundamental principle is the basis of the Quebec Charte des droits et libertés de la personne (the Quebec Charter of Human Rights and Freedoms) and the Canadian Charter of Rights and Freedoms. Equality among people is mainly relevant to reflection about preimplantation genetic diagnosis because of the possible consequences of selecting embryos with a view to preventing the birth of persons with particular diseases or carrying particular susceptibility genes\*.

More globally and in the long term, in the event some indications for PGD were accepted, it would be important to pay closer attention to the consequences of such acceptance on people struggling with these diseases and on those closest to them. Knowing that it is possible to diagnose a genetic disease, it is all-important to ensure that children born after such a diagnosis are not stigmatized, that support services offered to their parents are not reduced and that the integration of these people into society is not compromised.

Similarly, authors and caregivers are concerned about the possibility of a form of long-term stigmatization of people with such diseases. They fear that the enthusiasm of researchers and the concentration of resources available for research to improve techniques will reduce research efforts to treat diseases that these diagnostic techniques make it possible to identify. If PGD is becoming more efficient and more affordable, will a lot of research still be conducted on the treatment of genetic diseases?

Given the development and improvement of PGD,<sup>384</sup> the Commission fears an eventual increase in social intolerance towards people or patients with severe disabilities. Could the very possibility of avoiding the birth of seriously ill persons or carriers of defective genes or susceptibility genes contribute to an increasingly demanding social redefinition of normality? This question refers to the concept of disabilities resulting from more of a social than a medical definition.<sup>385</sup> The Commission is also concerned about the influence that certain state measures could have on the reproductive autonomy of individuals (reimbursement of costs associated with screening for specific diseases, for example). Don't universal screening programs pose an indirect challenge to the value of equality among people by suggesting that society is willing to deploy significant resources to prevent the birth of people with a particular disease? Ultimately, embryo selection raises fears associated with any eugenic practice (see box on this subject).

383 See among others, C. McLEOD, *Self-Trust and Reproductive Autonomy*, Cambridge, The MIT Press, 2002, vol. 57 and K. HARWOOD, "Egg freezing : a breakthrough for reproductive autonomy?", *Bioethics*, 2009, vol. 23, n° 1, pp. 39-46.

384 Again, it should be noted that this also applies to other diagnostic techniques such as PND.

385 B. STEINBOCK, "Ethical differences between inheritable genetic modification and embryo selection", in Audrey CHAPMAN *et al.* (eds.), *Designing our Descendant: The Promises and Perils of Genetic Modifications*, Baltimore, The Johns Hopkins University Press, 2003, p. 182.

## STATE EUGENICS, LIBERAL EUGENICS: TWO DISTURBING PHENOMENA

- “*State eugenics* is an ideology that creates and implements the most favourable conditions for procreation in order to improve the human species.”<sup>386</sup> This ideology now has a clearly unacceptable character in democratic societies, particularly because it did not respect individual autonomy and liberty relating to reproduction. As its name implies, this type of eugenics is incorporated in programs set up by a State.
- *Liberal eugenics* actually refers to fears of eugenic abuses based on individual choices parents make, using different techniques of assisted procreation, and on the development of knowledge (and therefore sometimes of opportunities) resulting from genetic engineering. Specifically, far from seeking to improve the human species, the reproductive choices of free individuals “simply guide the destiny of a certain number of individuals.”<sup>387</sup> The fears of eugenic drifts result less from the fact some couples try diagnostic methods to avoid giving birth to children who will develop severe disease, and more from the threat posed by the expanded indications for diagnosis (either prenatal or preimplantation). It is therefore not so much the State that forces the hands of citizens, than citizens themselves who take decisions in their personal capacity. Could the unrestricted autonomy of parents lead to demands for the sake of convenience (eye colour, sex, physical strength, etc.) that were less and less related to the prevention of illness and more to social standards?

## PRACTICE AND ETHICAL ISSUES

Before preimplantation genetic diagnosis was developed, and considering that some form of selection has always been made through *in vitro* fertilization, prenatal diagnosis used to be the only method of genetic analysis for determining the status of an embryo.

PGD is now offering new and far broader applications than those normally leading to PND. In fact, although all indications for PGD raise ethical issues, not least those related to the safety of the procedure, the most recent applications of PGD – which move away from the objectives of and indication for PND – generate the most discussion. These indications can be grouped under the following categories:

- 1) Diagnosis to increase the chances of successful IVF;
- 2) Diagnosis to ensure the health of the child;
- 3) Diagnosis seeking to benefit a third person;
- 4) Diagnosis to satisfy non-medical indications.

These broad categories are helpful here for understanding the various reasons for PGD and identifying the most important ethical issues, but it should be emphasized that clinical situations often make it difficult to distinguish between them.<sup>388</sup>

### Diagnosis aimed at increasing the chances of assisted procreation succeeding

In the case where a couple resorts to *in vitro* fertilization, it is important to note that even if no preimplantation genetic diagnosis is considered, a selection of embryos takes place. Indeed, since the number of embryos may be higher than it is desirable to implant, the embryos are selected on the basis of observations to identify the ones most likely to develop after implantation and to promote the success of assisted procreation. This selection is usually based on the following criteria: the appearance of cells, their number, how they are assembled, the rapidity of their development. In contrast to PGD, this selection is not, however, based on genetic analysis.

386 Jean-Noël MISSA, “Eugénisme d’État”, in Gilbert HOTTOIS and Jean-Noël MISSA (eds.), *op. cit.*, p. 421 (our translation).

387 Jean-Noël MISSA, “Eugénisme privé”, in Gilbert HOTTOIS and Jean-Noël MISSA (eds.), *op. cit.*, p. 426 (our translation).

388 As underlined in the previous section, people resorted to PGD may for example seek successful treatment for their infertility problem and seek to avoid transmitting a genetic disease to their child.

Recently, it was also proposed to use PGD to improve the selection of embryos to identify carriers of aneuploidy. Indeed, as was mentioned at the beginning of this chapter, aneuploid embryos have an abnormal number of chromosomes, resulting in the majority of cases in implantation failure or miscarriage. By identifying embryos with chromosomal abnormalities (e.g. trisomies), the idea is to increase the chances of assisted procreation succeeding. This kind of procedure, which is distinguished from PGD, is called “preimplantation genetic screening” and may be intended for all couples or individuals resorting to assisted procreation, whether or not there is a risk of transmitting an anomaly or genetic disease to their offspring. The main purpose of this type of PGD would be to increase the chances of assisted procreation succeeding and not of avoiding the birth of children carrying or affected by inherited conditions.

It is debatable how effective using PGD may increase the chances of AP succeeding. Recent studies have shown that this procedure could actually be harmful and reduce pregnancy rates,<sup>389</sup> or at least that it did not appear to improve the implantation rates or live births.<sup>390</sup> However, other authors claim the opposite, while stressing the need for further research in this area.<sup>391</sup> Nowadays, debate particularly seems to focus on the benefits of using this technique in women who have experienced multiple miscarriages or who have experienced failure in previous AP attempts, or those who are of an advanced age.<sup>392</sup> For example, a clinic in Quebec reported 52% of pregnancies and 25% of implantations when PGD was performed in women over 37 years of age. In this same clinic, when PGD was performed after repeated miscarriages, it led to outcomes of 41% of pregnancies and 23% of implantations, which was higher than without PGD and among 37-year-old women who did not resort to PGD.

Nevertheless, and despite the fact that PGD aimed at increasing the chances of AP succeeding is available in a large number of US clinics,<sup>393</sup> several professional organizations agree that more research should be conducted to determine the true benefits and indications of such use of PGD.<sup>394</sup> Several recommendations have indeed been made along these lines. For example, the Society of Obstetricians and Gynaecologists of Canada and the British Fertility Society recommend that this type of PGD be offered in a clinical study framed in a real research protocol and they stress the importance of an appropriate statement of risks and uncertainties associated with this procedure.<sup>395</sup>

The Commission also notes that other recent scientific developments suggest that it could be possible to meet the same objectives of this type of PGD, with procedures involving less risk to the parties concerned and not requiring the removal of cells(s) from the embryo.

In ethical terms, given that this use of PGD aims solely to increase the chances of AP succeeding, the Commission believes that it should be distinguished from uses aiming to prevent the birth of children with genetic or chromosomal abnormalities, and which are discussed in the next sections of this position statement. Indeed, compared to pregnancies resulting from natural conception, pregnancies resulting from IVF are associated with a higher risk of miscarriage, of prematurity (which leads to multiple consequences for the child, of varying degrees of severity), of intra-uterine stunting, malformations or congenital diseases. Accordingly, if it proved possible to avoid such risks by undertaking PGD, and if the benefits of such a procedure were confirmed scientifically, then this type of PGD could meet the basic requirements ensuring the well-being of individuals using AP and children resulting from the procedure. In such conditions, it would make it possible to avoid complications or failures whose effect on the health of the mother, but also possibly on that of the child, can be significant.

However, the Commission is particularly concerned about the prospect that this type of PGD were to become widespread, it would amount to systematic genetic screening of embryos with abnormalities such as trisomy 21, which raises major ethical and social issues. The Commission therefore stresses the importance of respecting this particular objective of PGD, namely to improve the chances of assisted procreation succeeding and not preventing the birth of children with chromosomal or genetic abnormalities, and reiterates the need to avoid slippage towards systematic screening of genetic conditions in pursuit of some other objective.

*Whereas PGD for the purpose of increasing the chances of success of AP is not a recognized and proven procedure and considering that current scientific controversies fully justify adopting a prudent approach, the Commission recommends:*

### Recommendation No. 12

That PGD for the purpose of increasing the chances of assisted procreation succeeding be only offered:

- Where specific medical indications are met;
- As part of a research protocol which has been subject to scientific and ethical review.

- 389 Sebastiaan MASTENBROEK *et al.*, “*In vitro* fertilization with preimplantation genetic screening”, *The New England Journal of Medicine*, 5 July 2007, vol. 357, n° 1, p. 9.
- 390 L. MEYER *et al.*, “A prospective randomized controlled trial of preimplantation genetic screening in the ‘good prognosis’ patient”, *Fertility and Sterility*, 2009, vol. 91, n° 5, pp. 1731-1738.
- 391 J. MERSEREAU *et al.*, “Preimplantation genetic screening to improve *in vitro* fertilization pregnancy rates: a prospective randomized controlled trial”, *Fertility and Sterility*, 2008, vol. 90, n° 4, pp. 1287-1289.
- 392 Anver KULIEV and Youri VERLINSKY, “Preimplantation genetic diagnosis: a realistic option for assisted reproduction and genetic practice”, *Current Opinion in Obstetrics and Gynecology*, 2005, vol. 17, n° 2, pp. 179-183.
- 393 S. BARUCH, D.J. KAUFMAN and K.L. HUDSON, “Preimplantation genetic screening: a survey of *in vitro* fertilization clinics”, *Genetics in Medicine*, 2008, vol. 10, n° 9, pp. 685-690.
- 394 See Sirpa SOINI *et al.*, “The interface between assisted reproductive technologies and genetics: technical, social, ethical and legal issues”, *European Journal of Human Genetics*, 2006, vol. 14, p. 597.
- 395 According to the Society of Obstetricians and Gynecologists of Canada, current outcomes with respect to these problems do not support resorting to preimplantation genetic screening: SOCIETY OF OBSTETRICIANS AND GYNECOLOGISTS OF CANADA, *op. cit.*, pp. 772-773. Along these same lines: AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE, *op.cit.*, pp. S141-142; R.A. ANDERSON and S. PICKERING, “The current status of pre-implantation genetic screening: British Fertility Society Policy and Practice Guidelines”, *Human Fertility*, June 2008, vol. 11, n° 2, pp. 71-75; EUROPEAN SOCIETIES OF HUMAN GENETICS *et al.*, “The interface between assisted reproductive technologies and genetics: technical, social, ethical and legal issues. Recommendations of the European Societies of Human Genetics and Human Reproduction and Embryology”, *European Journal of Human Genetics*, 2006, vol. 14, pp. 509-511.

## Diagnosis aimed at the health of the child

The main objective of preimplantation genetic diagnosis is the detection of genetic diseases or abnormalities with a view to avoiding the birth of children likely to develop diseases after birth. The ethical issues raised by PGD aimed at the health of the child vary, depending on whether monogenic diseases are at stake, or recessive diseases, certain disease-susceptibility genes (for example cancer) and late-onset diseases.

### The diagnosis of monogenic diseases

Before going further, the Commission considers it necessary to define certain concepts in genetics so the reader can more easily grasp its purpose. These explanations are summarized in the following box:

#### SOME BASIC CONCEPTS IN GENETICS

Each individual receives 46 chromosomes from its biological parents, including 23 from its mother and 23 from its father. Chromosomes (with the exception of sex chromosomes) are called homologous (or autosomal) and have significant genetic similarities. Chromosomes consist of the same genes, in other words they have the same basic DNA sequences, but the genes of parents carry variations or mutations. The child coming into the world will carry two copies of the same gene from its biparental inheritance.

So-called hereditary diseases can be attributed to mutations present in a single gene (monogenic disease), several genes (polygenic disease) or genetic factors related to environmental factors.

In the case of monogenic diseases, a single defective gene causes the onset of the disease. This gene can be dominant or recessive: such a disease is therefore dominant or recessive.

- A dominant disease is expressed when an individual carries one copy of the dominant gene.
- A recessive disease is expressed when an individual carries two copies of the gene affected by the mutation. When an individual has a single copy of the gene affected by the mutation, it is carrying the disease but the disease will not develop. Later, however, this individual could pass the gene on to its children. An individual may also be carrying two copies of the gene not affected by the mutation.

This model of PGD is intended for couples or individuals who know they are at risk of transmitting a genetic defect to their children that causes genetic disease. PGD can be used to diagnose major monogenic diseases such as cystic fibrosis (or mucoviscidosis), spinal muscular atrophy, myotonic dystrophy (or Steinert's disease) and sickle cell anemia\*. The following sex-linked diseases may also be screened: Duchenne muscular dystrophy, hemophilia\*, adrenoleukodystrophy\* and Hunter syndrome\*.

To date, no general genetic screening technique is able to detect all monogenic diseases. In all cases of diagnosis of hereditary monogenic disease, it is therefore necessary to identify the disease whose presence is being sought. In other words, it is necessary to diagnose the mutation responsible for the disease in a parent in order to localize the gene that PGD is used to analyse. Tests conducted on an *in vitro* embryo can determine if it is carrying hereditary trait that would be responsible for a monogenic disease affecting one of the parents (in the case of autosomal dominant diseases) or if the carrier of one or two copies of the gene, whether this carrier was affected or not by the mutation (for recessive diseases). The goal is to transfer into the mother's womb only those embryos that do not carry the gene.

Among hereditary diseases for which PGD is most often sought, some cause severe disability or cause the death of children after birth or at a very young age.

Cystic fibrosis is a frequent indication for PGD. It is a severe autosomal recessive disease. The most common clinical form of cystic fibrosis involves respiratory, digestive and growth disorders. It is a disease of chronic and progressive evolution, often appears in early childhood and causes death from chronic respiratory failure. The median age of survival for people with this disease is 37 years.

Other diseases, such as Huntington's disease, appear later in the life (usually around the age of 30). Huntington is a dominant hereditary disease. The Commission, following the example of many authors,<sup>396</sup> considers that this disease falls in the category of monogenic diseases.<sup>397</sup> Yet it seems that some people have developed the disease whereas they had the normal (nonmutated) gene. Three other genes are suspected in the onset of this disease.<sup>398</sup>

396 See for example the COMMISSION NATIONALE D'ÉTHIQUE POUR LA MÉDECINE HUMAINE, *op. cit.*, p. 11 and Sirpa SOINI *et al.*, *op. cit.*, p. 12.

397 A. DURR and S. VIVILLE, "Maladie de Huntington: l'expérience du test présymptomatique du diagnostic prénatal et préimplantatoire", *Gynécologie Obstétrique & Fertilité*, October 2007, vol. 35, n° 10, pp. 1051-1054.

398 A study undertaken among 252 patients presenting characteristic symptoms of Huntington's disease but who tested negative for the mutation responsible for this disease. Two other genes have since been identified. These genes would be responsible for 3% of cases of Huntington's disease. A third gene could be involved but was not the focus of the study. (Giovanni STEVANIN *et al.*, "Huntington's disease-like phenotype due to trinucleotide repeat expansions in the *TBP* and *JPH3* genes", *Brain*, 2003, vol. 126, pp. 1599 and 1602).

## **THE LATE ONSET OF DISEASE AND THE NON-DISCLOSURE OF DIAGNOSIS\*: THE CASE OF HUNTINGTON'S DISEASE**

In cases where an individual's father or mother suffers from Huntington's disease, the individual knows there is a 50% chance of developing it, since this is a dominant disease. Since symptoms usually appear when the offspring of an individual with Huntington's disease reaches the age to have a parental project of their own, one thing is clear: if the child of an individual with Huntington's disease, on reaching adulthood in turn, then procreates naturally, and if PND is performed and reveals that the fetus has the mutation responsible for Huntington's disease, then the parent of the fetus will learn that he will inevitably develop the disease at a later date. Considering this individual probably has several years to live in health, he may prefer not knowing about this inescapable personal fate.

In such a situation, PGD stands as an alternative to PND, not only to prevent the birth of a child with a genetic disease, but also to respect the individual's desire not to know if it carries the gene which inevitably leads to onset of the disease. This indication for PGD is commonly known as non-disclosure of diagnosis; it implies that specialists performing PGD on embryos will only transfer non-carrier embryos (without specifying whether available embryos included carrier embryos). People resorting to PGD in these circumstances thus hope not to know their genetic status, while avoiding the situation where their descendants would have to grapple with such a dilemma and such a disease.

To the extent that a person is at high risk of being affected with Huntington's disease as soon as direct ancestors are or have been affected, access to PGD of this genetic disease does not raise ethical issues fundamentally different from those related to PGD of other serious monogenic diseases. However, the particular conditions of the process for non-disclosure are subject to debate. The medical team may face a dilemma: what happens if all embryos are carriers and the physician cannot transfer embryos? How will this be explained to, or hidden from, parents? According to one clinic consulted by the Commission, physicians generally agree with couples or individuals on all possible options. Ultimately, this case falls within the domain of medical ethics.

A PGD procedure that makes it possible to select embryos not carrying the gene for a monogenic disease and to implant them into the uterus acknowledges the value of the child's well-being and the concern to respect the reproductive autonomy of individuals. Indeed, this PGD application seeks to fulfil a primary objective: to enable a couple or person knowing they are at risk of conceiving a child with a hereditary disease from having a child biologically related to them and nonetheless healthy. Unlike prenatal diagnosis, preimplantation genetic diagnosis saves them the stress of having to opt for abortion if natural conception led to creation of a fetus that would develop the disease. In this situation, the use of PGD is intended as an alternative to PND as long as the couple involved is able to appreciate the fact that the risks and inconvenience associated with IVF are less significant than difficulties related to abortion.

Additional distinctions can be drawn about this use of PGD as an alternative to PND, given the risk of errors inherent in PGD. It is often recommended to confirm PGD by performing PND. PGD reduces the likelihood of a positive prenatal diagnostic test followed by an abortion, but a risk of spontaneous abortion is associated with PND, in addition to specific PGD-related risks for the embryo. One of the greatest centres performing PGD (the Reproductive Genetics Institute in Chicago) provides its clients with an information document stating that PGD is no substitute for PND.<sup>399</sup>

Moreover, at present, the ethical justification to conduct diagnostic tests on an embryo to determine if it carries hereditary traits is based primarily on the value of the child's well-being. This clinical intervention can prevent the child to be born from facing a disease that could significantly affect its quality of life.

The Commission is guided by its concern for the child's well-being, and therefore proposes a path between the primacy of individual liberty and the unconditional refusal of PGD which some people call for, in the name of human dignity and equality. The desirable way to balance the values just considered is by:

- limiting access to PGD, which would be offered to parents at risk of conceiving a child with a severe monogenic disease involving irreversible handicaps for the child;
- offsetting access to PGD by a strengthened commitment to ease the integration of persons with disabilities or suffering from these serious diseases, by means of social policies protecting their rights and promoting their integration into society.

399 REPRODUCTIVE GENETICS INSTITUTE, *PGD for Single Gene Disorders*, 2007, [online], [http://www.reproductivegenetics.com/single\\_gene.html](http://www.reproductivegenetics.com/single_gene.html).

Furthermore, the autonomy of the person involves a “capacity” to discharge a certain freedom of choice and action. Accordingly, with the aim of combining the use of PGD with respect for the reproductive autonomy of individuals, it is important that parents be adequately informed and receive psychological support in order to take a truly free and informed decision. Among other things, it is essential that they understand the risks associated with the practice of PGD. In addition, parents should understand that the accuracy of PGD cannot be absolutely guaranteed, not only because this practice is still considered experimental, but also because all the risks the procedure may pose to the health of children are not yet known.

Once the use of PGD is justified by the medical indication for the diagnosis of monogenic diseases that could significantly affect the quality of life of the child, the question arising concerns identifying indications. It is no easy task to objectively determine the medical indications likely to justify PGD, since such a determination involves the concept of quality of life. The Commission is aware that the assessment of quality of life of a person refers to subjective criteria influenced by socio-cultural determinants. The Commission notes that there is a risk of extending the procedure for other indications. As a way of avoiding this slippery slope, the Commission uses some inclusion criteria for determining which diseases are considered as medical indications for PGD: the severity of disease, its inevitability, its generally severely debilitating or fatal character, and the absence of treatment. This list of criteria is not exhaustive and some borderline cases may arise.

Moreover, the question mentioned above about a parents’ hypothetical *duty* to select embryos not carrying a disease, raises the question of responsibility. Is it the responsibility of parents, clinicians or the State to determine the ethical acceptability of PGD, to specify indications and to select an embryo to be implanted? “Who decides to perform an existing procedure and based on which values?”<sup>40</sup> While it is indisputable that parents must play an important role in decisions affecting their parental project, this individual liberty is perhaps not sufficient when a decision needs to be taken on the ethical justification of indications for the selection of embryos. Where determining the indications for a procedure such as PGD are concerned, it is hard to imagine that prospective parents could be left alone to face the multiple possibilities of this procedure. It is also hard to let clinicians take such decisions alone. More generally, it is clear that society is involved and should therefore take part in these decisions.

*Whereas the collective determination of medical indications for PGD would ensure a balance between the privacy of a parental project, the responsibility of the parties with respect to the health and well-being of the child as well as respect for the equality and dignity of persons, the Commission recommends:*

### **Recommendation No. 13**

That access to PGD be open to couples or individuals with a known risk of conceiving a child with a serious, severely debilitating or fatal inherited monogenic disease, for which there is no known treatment.

Also whereas it is difficult to determine how far the criterion of severity may be extended, without detailed consideration, the Commission recommends:

#### Recommendation No. 14

That the Minister of Health and Social Services grant a mandate to the Agence d'évaluation des technologies et des modes d'intervention en santé (AÉTMIS) to draw up a list of serious, severely debilitating or fatal monogenic diseases, for which there is no known treatment.

Some authors are concerned about the consequences of access to PGD to diagnose the presence of serious genetic diseases such as monogenic diseases. They fear that individuals who know they carry monogenic diseases and know they can select healthy embryos will feel morally obliged to undertake an IVF followed by PGD. The *possibility* of performing PGD could become a parental *duty* for some people. From these assumptions emerge the following questions. Since the technique exists, would parents who know they risk transmitting a serious illness be justified in not having IVF and PGD performed? If the procedure becomes less complex and easier to afford, are there grounds to fear some form of social pressure in favour of it? Will prospective parents always be autonomous and free to choose between natural procreation and IVF?

Although these questions concerning “undue pressure” also arise in the context of PND and other existing diagnostic methods, they nonetheless raise different issues in the case of PGD. Indeed, although PGD avoids the potential recourse to abortion, it still requires the acceptance of certain risks, notably for the woman undergoing the IVF procedure and the child resulting from the procedure. Moreover, expanding access to PGD could involve an over-medicalization of procreation, additional constraints and risks for women and an increasingly narrow definition of social normality and of embryo quality.

400 I. NISAND, “Le diagnostic préimplantatoire (DPI): entre fantasme et imprécation!”, *Gynécologie Obstétrique & Fertilité*, December 2007, vol. 35, n° 12, p. 1271 (our translation).

Finally, some authors consider as speculative those questions concerning the relationship between the possibility of offering PGD to avoid the birth of seriously ill children and discrimination or intolerance in the longer term towards people with disabilities. Nevertheless, while medical indications seem to justify embryo selection as a way of avoiding the birth of seriously ill children, a balance must be sought between respect for the dignity of persons living with disabilities and respect for the reproductive autonomy of prospective parents, including the possibility of preventing the birth of a child whose quality of life would be greatly and permanently diminished.

Faced with this risk of expanded uses of PGD, some authors are tempted to highlight the complexity and inconvenience of IVF as a way of suggesting that an expansion of indications is unlikely. On the other hand, several authors suggest that a rapid evolution of technology is possible:

« For now, the cost, burden and constraints of the technique impose strict indications and limit the number of PGD centers, but technical problems will be solved in years to come and more and more opportunities will be offered to couples. For example, “biochips” will be able to recognize numerous configurations of DNA in a single cell.<sup>401</sup>



For some, the only limit on this evolution of PGD will be from ethical and legal constraints.<sup>402</sup>

It is therefore necessary to consider the possibility that a definition of PGD accessibility criteria could lead in the mid- or long-term to a certain collective standardization of the selection procedure for PGD access. The issue at stake here is knowing what social consequences such criteria for diagnosis indications would have and what interpretation people with disabilities and their loved ones would make of such criteria. Would people with disabilities face discrimination or stigmatization as a result of such criteria, or worse, if a formal list of indications for PGD were drawn up? The question goes to the heart of debates about liberal eugenics<sup>403</sup> – a form of discrimination against persons with long-term disabilities, resulting from standardized processes of embryo selection.

*Whereas risks are associated with open access to PGD for specific medical indications, the Commission recommends:*

#### **Recommendation No. 15**

That the Government of Quebec, in order to avoid eugenic practices, as well as discrimination against and stigmatization of people with genetic diseases or genetic abnormalities, improve and set up programs:

- To meet their needs and those around them and
- To promote the integration of these persons into society.

## The diagnosis of embryos that are heterozygous carriers of genes for a recessive disease

While the Commission considers that it is acceptable to make PGD available in cases where the child may develop a serious genetic disease, it does not consider the diagnosis of embryos that are heterozygous carriers<sup>404</sup> of genes for a recessive disease to be an equally acceptable justification for PGD. This type of diagnosis would be aimed at rejecting embryos carrying a recessive genetic mutation, that is, embryos not at risk of developing the disease after birth.

The main reason people use PGD for this purpose would not be to prevent the birth of a sick child (since the risk in their case has been removed), but rather to prevent the birth of a carrier child who will, on reaching adulthood and once ready for a parental project, face complex reproductive decisions.<sup>405</sup>

Yet, is it ethically acceptable to undergo PGD for the primary purpose of rejecting such embryos and knowing they are unlikely to develop the disease? These children will not live with a serious, incurable and disabling illness. They will have to make reproductive choices in adulthood, in the event that their spouse also carried the same genetic abnormality, but they will have access to PND and eventually to PGD, or they may be able to seek alternatives such as adoption or gamete donation.

*Whereas this is a situation where the costs outweigh the benefits that would like accrue to society as a whole and to individuals from such an indication for PGD, the Commission recommends:*

### Recommendation No. 16

That access to preimplantation genetic screening not be permitted for the sole purpose of screening embryos that are heterozygous carriers of a recessive disease, that is to say, in cases where one parent is a heterozygous carrier of such a disease.

401 Anver KULIEV and Youri VERLINSKY, *op. cit.*, p. 182.

402 Sigal KLIPSTEIN, "Preimplantation genetic diagnosis: technological promise and ethical perils", *Fertility and Sterility*, 2005, vol. 83, n° 5, p. 1349.

403 See on this subject Jürgen HABERMAS, *L'avenir de la nature humaine: vers un eugénisme libéral?*, Paris, Gallimard, 2002.

404 The term *heterozygous* designates an individual carrying two different copies of a gene (the first healthy and the second affected by the mutation); the term *homozygous\** designates an individual carrying two identical copies of the gene affected by the mutation.

405 Indeed, if one of the two spouses is the healthy carrier of a recessive disease, then each embryo has a 50% probability of being a carrier as well, without running the risk of developing the disease after birth. If both spouses are carriers, each embryo has a 50% probability of being a heterozygous carrier (and therefore of not developing the disease) and a 25% probability of being a homozygous carrier (and therefore of developing the disease after birth). PGD therefore enables couples both of whose members are carriers of the gene to reject homozygous carrier embryos and, when possible, to also reject heterozygous carrier embryos with a view to reimplanting only embryos without the disease gene. In the case where two members of a couple are heterozygous carriers, the indication for PGD falls in the first category, namely that of seeking to avoid the birth of a very sick child. See the definition of *carrier embryo* in the glossary and the probability diagram in appendix 4.

### The diagnosis of susceptibility genes

The analysis of susceptibility genes aims to identify embryos with a gene predisposing them to develop a disease during their lifetime.

The child carrying the susceptibility gene will not necessarily suffer from the disease in question, because these diseases are multifactorial, that is they are not only caused by a genetic predisposition, but result from a combination of several genes and factors such as the environment, diet, smoking and other lifestyle habits. The decision to reject embryos carrying the susceptibility gene implies rejecting some embryos that would never have developed the disease. Conversely, embryos selected because they are not carriers of the susceptibility gene could develop this type of disease due to exposure to environmental risk factors, for example. This is therefore a matter of screening rather than of diagnosis, since the idea is not to be *certain* that the child will actually have the disease, but rather to *estimate the risk* that the child will develop the disease in adulthood. Alzheimer's disease<sup>8</sup> is often mentioned in this category.

## ALZHEIMER'S DISEASE

Alzheimer's disease is a late-onset disease whose causes are not yet fully known. There is a purely genetic form of this disease, which would appear to affect about 7% of patients. There are also genetic predispositions to the most common form called sporadic, but genetics is not solely responsible for the onset of the disease and several risk factors remain unknown. In general, performing PGD of susceptibility related to the development of Alzheimer's disease is not just controversial; it is also not considered absolutely reliable.<sup>406</sup>

The ethical acceptability of this form of PGD will depend on the justification for resorting to embryo selection, taking into account the *risk* of developing serious illness. Again, the argument in favour of this risk estimate is the child's welfare. Indeed, if a disease is serious, debilitating and potentially fatal, and if it could risk developing where the embryo carries susceptibility genes, then it might be tempting to see the same justification as in the case of an embryo diagnosed as a carrier of the disease.

According to current thinking, it is more probable that multifactorial diseases will be prevented by adopting healthy lifestyles in a healthy environment than by using PGD to screen for susceptibility genes. In addition, although treatments for these diseases sometimes seem inadequate, they do exist.

*Whereas in the present state of knowledge, this type of disease – including some cancers such as breast cancer – cannot be classified in the same category as diseases constituting indications for PGD, the Commission recommends:*

### Recommendation No. 17

That preimplantation genetic diagnosis not be used to screen an embryo with susceptibility genes to multifactorial diseases.

### Diagnosis for the benefit of the health of a third party

Some fertile couples who have a child with a serious disease seek preimplantation genetic diagnosis. A recent application of PGD consists in developing an *in vitro* embryo, which on the one hand is not a carrier of a genetic disease and on the other is selected for histocompatibility lymphocyte antigen (HLA), so that it is immunologically compatible with a brother, sister or sick relative whose survival depends on marrow or stem cells\* extracted from umbilical cord blood.<sup>407</sup> In the case of this application, the indication for PGD is the desire to conceive and select an embryo destined to become a donor, hence the designations “designer baby”, “donor baby”, “double hope baby” or “saviour child”.

In France, the first child destined to serve as a donor for one of its siblings was born October 5, 2000. According to data collected by the PGD Consortium in 2004, for 45 centers around the world having performed a total of 3,530 PGD procedures, seven procedures involved HLA typing.<sup>408</sup> In Quebec, a fertility clinic refuses to perform HLA typing, because it fears that this could lead to drifts. Another clinic performed PGD after applying to the ethics committee and receiving its approval. Elsewhere in the world, Fanconi anemia and leukemia\* are two examples of diseases for which parents have used PGD for HLA compatibility.

Fanconi anemia is a genetic disease that appears in a child from the age of six years; when untreated, the child may die between the ages of 15 and 20. The treatment involves grafting stem cells derived from the umbilical cord blood of a compatible child.

406 ALZHEIMER SOCIETY, *Alzheimer's Disease and Genetics: The role of genes in Alzheimer's disease*, July 2007, [online], <http://www.alzheimer.ca/english/disease/causes-heredity.htm>. Also see the report on Alzheimer's disease and current research for more details on susceptibility genes and other risk factors: Jack DIAMOND, *A Report on Alzheimer's Disease: Current Research*, Alzheimer Society of Canada, 2006, 17 p., [online], <http://www.alzheimer.ca/docs/ASLayBookletEng%204.pdf>.

407 Héma-Québec manages a public bank of cord blood. The blood is retrieved after the birth of the child, once the umbilical cord has been severed. The retrieval is less invasive than retrieval of bone marrow and is without danger for either mother or child. The donation of cord blood is indicated for individuals under 50 kg [the amount retrieved is not sufficient for individuals over 50 kg]. (HÉMA-QUÉBEC, *Sang de cordon ombilical*, 2008, [online], <http://www.hema-quebec.qc.ca/francais/cellulesouches/sangcordon.htm>).

408 EUROPEAN SOCIETY OF HUMAN REPRODUCTION AND EMBRYOLOGY (ESHRE), “Inside the PGD Consortium”, *Focus on Reproduction*, January 2007, p. 19, [online], [http://www.eshre.com/binarydata.aspx?type=doc/Focus\\_article\\_jan07.pdf](http://www.eshre.com/binarydata.aspx?type=doc/Focus_article_jan07.pdf).

According to Arnold Munnich and Stéphane Viville, at the Centre de DPI de Strasbourg (France), it is “unrealistic” to offer parents the option of conceiving a healthy and compatible child, given that the chances of success are very slim:<sup>409</sup> the probability of having a healthy and compatible embryo is 3 chances in 16.<sup>410</sup> Couples often have to go through several cycles of *in vitro* fertilization to reach this goal. Moreover, for this procedure to succeed (it requires the birth of a compatible donor), the sick child needs to be able to survive long enough for the IVF procedure to be performed and the pregnancy to be carried to term (minimum one year).

In fact, several scenarios can happen and prevent the successful birth of a healthy and compatible child:

- 1) the fetus may be miscarried;
- 2) HLA compatibility may not be of the right kind or may be insufficient (PGD is not 100% reliable in this regard);
- 3) the graft can fail;
- 4) the graft of cord blood stem cells may not be sufficient to treat the sick child and other grafts may be needed later.

The collection of stem cells in cord blood does not physically interfere with “the child donor”, but the treatment with stem cells may not cure the brother, sister or relative; in such cases, one or more bone marrow transplants could be considered. Indeed, the Council of Europe raises the possibility that the collection of umbilical cord blood is impossible or insufficient.<sup>411</sup> Parents could then request the more intrusive procedure of removal of bone marrow, or start another *in vitro* fertilization procedure with PGD in an attempt to give birth to another child donor:

« The graft will not necessarily be successful. In family cord blood transplants, the rate of 5-year survival of patients with Fanconi anemia is approximately 70% (against 44% for unrelated grafts). An excellent figure compared to other diseases which can be treated with marrow transplantation. But 70% is not 100%. For the child recipient is particularly at risk of infection: it is deliberately immunocompromised just before transplantation, and remains so throughout the period of colonization of the transplanted marrow stem cells. Moreover, there is a risk that the graft will not “work”, for example if the number of cord stem cells is not high enough.<sup>412</sup> »

In theory, PGD of HLA compatibility can be performed in order to make a simultaneous selection based on two objectives:

- The first is to reject embryos carrying a genetic mutation (negative selection);
- The second is to identify, in the non-carrier embryos, an embryo compatible for HLA tissue groups with a person already born who suffers from the disease (positive selection).

This dual purpose is actually mentioned in the case where the living child is suffering from Fanconi anemia. However, unlike this disease, leukemia is not an inherited disease. It is a cancer affecting blood cells and can occur in any child. The genes responsible for this disease are not known and leukemia can be treated by donated bone marrow.<sup>413</sup> In the case of such a disease, conceiving a child through *in vitro* fertilization with PGD has only one purpose: since the probabilities are very low that the subsequent child in the family will develop the same non-hereditary disease, PGD is actually performed as a way of preparing a compatible donor.

The question arising in the context of this type of indication for PGD is not so much the question of negative selection, which is common to other previously mentioned forms of PGD, as the question of the positive selection occurring: the implanted embryo is not selected solely because it will not develop serious illness, but also because it has a genetic characteristic that will make it a cord blood or bone marrow donor for a family member.

The selection of embryos based on specific criteria is generally assessed according to its purpose: if positive selection was motivated by a racial judgment, for example, then it would be wrong and doubtless would be condemned in society. In the case of PGD for compatibility, the selection criterion is based on a relational dimension: compatibility between the child to be born and the child or relative who is already out in the world, but who is sick. It should be noted that this selection is focused on fulfilling the needs of a third party: the survival of the sick child or relative.

The main concerns expressed about the welfare of the child arising from this practice include, among others, its psychological development and its identity. In this situation, the Commission places the values of dignity and respect for the symbolic freedom of the child at the core of its reflection, and also highlights the negative physical and psychological changes that may affect the stakeholders involved.

409 Cécile KLINGLER, "Ces improbables bébés médicaments", *La Recherche*, February 2004, n° 372, p. 50.

410 A.R. THORNHILL *et al.*, "ESHRE PGD Consortium 'Best practice guidelines for clinical preimplantation Genetic diagnosis (PGD) and preimplantation genetic screening (PGS)'", *Human Reproduction*, 2005, vol. 20, n° 1, p. 37.

411 Julie COUSINEAU, *op. cit.*, p. 438.

412 Cécile KLINGLER, *op. cit.*, p. 48 (our translation).

413 Héma-Québec's website states that the donation of bone marrow requires hospitalization for 24 hours, pain is slight and complications are rare. From 3 to 5% of a donor's marrow is generally retrieved (an adult requires about one litre of marrow), which will be regenerated in the three to four weeks following the operation. (HÉMA-QUÉBEC, *Don de moelle osseuse*, 2008, [online], <http://www.hema-quebec.qc.ca/francais/cellulesouches/registre/moelleosseuse.htm>).

From the outset, conceiving a child in order to meet the therapeutic needs of a family member necessarily constitutes a form of instrumentalization; the Commission cannot support such a practice. The Commission analysed several scenarios in order to reach this position and validate its point of view.

In a first case, a couple or individual could inform the medical team at the outset that it is ready to go ahead with an IVF procedure with PGD, although it does not want the child. It only wants cord blood. This extreme demand, which has already been made of one fertility clinic, would appear to be motivated solely by the production of tissues of therapeutic value.

In a second case, a couple apparently wants to give birth to the child, but faced with a situation where no compatible embryo is generated, the couple may reject all embryos, admitting *a posteriori* that the child was not wanted for itself.

In a third case, a couple whose desire to have children is obvious and who resort to IVF (due to impaired fertility) and PGD (to prevent the transmission of a serious illness) may apply to the medical team to select and implant healthy *and* compatible embryos with sick child or relative. Even in this case, the Commission considers that a form of instrumentalization is involved.

For the Commission, any violation of the principle of non-instrumentalization of human beings would not only be an affront to human dignity, but would also open the door to drifts – even where the objective was to save a child or relative (a noble cause if ever there was one), although the measures taken were incompatible with the respect that human beings deserve. Should every measure be taken to save the life of a sick child? Are all measures morally acceptable? By answering “no” to these questions, the Commission considers that approving of this kind of “reparative medicine” would amount to allowing for the production of human beings without any consideration for their dignity.

The selection of embryos based on their immunogenetic compatibility also runs the risk of undermining the symbolic freedom of the child: in such cases, the resulting child would be “determined” by the willingness of its parents that it assume a specific role, which constitutes a violation of its physical integrity. Some arguments relativize this issue by lining it up alongside other motivations behind the parental project: “Is wanting a child and seeking at the same time to save a life so different from wanting a second child so the first child will have a playmate?”<sup>414</sup> However, in terms of symbolic freedom, there is a real difference between a child whose parents are planning or hoping that it will maintain a harmonious and intense relationship with its brother or sister, and a child “selected” on the basis of specific genetic characteristics that define him/her as a donor. In the first case, the child has a margin of autonomy that allows communication with its parents, whereas in the second case the child is born *to* save a sibling or relative. This second child has no part in the decision imposed on it, and no part in the role assigned to it.

Due consideration should also be given to the psychological risks for the child and for the construction of its personality: is there a risk that it will only see itself as a “donor” for the benefit of a sick brother, sister or relative? Will it tend to see itself solely in terms of its “therapeutic” role? If the graft works, the feeling of having been the reason why a sibling or relative was healed could be thrilling. However, if the graft fails and the sick person dies, could the life of the child forever be marred by this failure, even though it can in no way be attributed to this child? Will the child see itself as the one who failed to save a sick brother, sister or relative, especially if this mission was the reason for its conception in the first place? Unfortunately, even though it is inevitable that such questions will arise about possible consequences, these considerations remain rather theoretical on the whole and do not make it easier to decide between the interests of the sick child or the unborn child.<sup>415</sup> However, in the context of reflection on the well-being of children, it is important to consider this *well-being* in a global perspective. In this sense, what seems most threatening in this practice is the psychological pressure that must be sustained by this human being, who for the family represents the therapeutic solution to a desperate situation.

Physical discomfort may also occur. Insofar as the donation of cells from cord blood involves no risk or discomfort for the infant, the question of the subjection of the designer baby arises more on the mid- to long-term if more grafts were deemed necessary.

The impact of such a procedure on the mother should not be underestimated. Not only does she submit to an IVF procedure, but she may experience pregnancy as a “difficult wait”:

« Any failure of this hypermedicalized pregnancy may be the cause of particular anxiety or a feeling of guilt on the part of the mother and those around her. Furthermore, the therapeutic purpose of saving the sick child may outweigh the specific expectation of the second child. It is quite conceivable that the worsening of the condition of the sick child could eventually lead the mother to consider a premature birth, in time, as has already been noted in certain circumstances to obtain cord stem cells in a timely manner.<sup>416</sup>



414 Jacques PONCIN, *op. cit.* (our translation).

415 CCNE, *Avis n° 72 Réflexions sur l'extension du diagnostic préimplantatoire, op. cit.*, p. 9.

416 *Ibid.*, p. 6 (our translation).

*Whereas there are risks to the value of respect for the dignity of the child and its welfare, as well as physical and psychological risks to stakeholders, and whereas the bank of umbilical cord blood managed by Héma-Québec is a promising alternative to help sick children, the Commission recommends:*

### **Recommendation No. 18**

- That the use of preimplantation genetic diagnosis for the selection of embryos be prohibited where the primary motivation is to conceive a donor of tissue or stem cells;
- That the collection of umbilical cord blood be encouraged in order to supply the public bank managed by Héma-Québec.

### **Diagnosis for non-medical reasons**

Non-medical reasons prompting people to resort to PGD are: wanting a child with a particular disability, sex selection of a child or ensuring that it is born with specific characteristics.

#### **The birth of children with disabilities**

Preimplantation genetic diagnosis allows the selection of embryos carrying an illness or disability to meet the wishes of those who are themselves suffering from this disability or illness, and who want to share this state with their child.

In 2002, in the United States, a couple of deaf women chose as a sperm donor a deaf man with several antecedents of deafness in his family. The couple thus increased its chances of conceiving a deaf child, using self-insemination. The couple's wish came true. Although most people consider deafness to be a handicap, this couple and many other deaf people do not consider it that way. According to this line of thought, deafness has more to do with cultural identity and it is wrapped up in a sense of belonging to that particular community. Moreover, according to this couple, deaf people now have better job opportunities than before (thanks to interpreter services, special schools and all the new technologies now available<sup>417</sup>). This example was not an indication for PGD. However, it is quite possible that clinics performing PGD receive this kind of application, which can in turn create some discomfort within clinical teams, as the following excerpt notes:

« Experts at the center readily comment on a question one of them had to resolve recently: a couple requested the implantation of an embryo obviously carrying the genetic defect that was supposed to be eliminated at the outset. The couple's argument: the embryo belongs to it, so it can dispose of the embryo as it pleases. The team finally accepted... and was very relieved to learn that ultimately the pregnancy failed. "We thought a lot about it, and we decided that in such cases, we would refuse to implant," says Professor Liebaers, "at most we would agree to hand over the embryo 'belonging to the couple,' without implanting it into the uterus ....".<sup>418</sup>



Once the status of available embryos is established, it is possible, using the genetic analysis techniques of PGD, to select carrier embryos instead of rejecting them. At the request of some people, centres outside of Canada have made such a selection.

According to the European Society of Human Reproduction and Embryology (ESHRE), this parental choice is only acceptable if it is based on the well-being of the child. Yet, if parents believe that the welfare of their child necessarily depends on being part of the existing family unit and the surrounding culture with respect to the disability in question,<sup>419</sup> then it is difficult to deny them access to genetic selection on the basis of disability.

Once the child reaches an age where it can dialogue on equal terms with its parents, it may however blame them for the irrevocable decision they took, which resulted in its having a serious reduced quality of life, at least in its own view. In fact, the child may be locked into a difficult psychological or existential paradox: if the child does not accept the state chosen for it by its parents, then it denies its own existence. This paradox is all the harder to bear, since it results from a deliberate parental choice.

Given the complexity of this argument, the Commission is aware that it can be applied to the decision of couples who face the results of PGD revealing that all their embryos suffer from grave defects, but who decide nonetheless to go ahead with implantation in fulfilment of their parental project. However, in this last case, the intention and the circumstances surrounding the decision are different from those of parents who want a sick or disabled child from the outset. In the first case, the primary intention is to conceive a healthy child, and this intention corresponds to the purpose of PGD; in the second case, this purpose is not respected in the couple's intention itself. Having said that, one should be aware that the argument of procreative autonomy can be invoked in these two situations, that is, to respect the couple's choice of implanting an embryo carrying a defect, no matter what the original intention may have been.

Moreover, requiring that couples or individuals with fertility problems or who know they risk transmitting genetic diseases to only have healthy children would amount to a new form of State eugenics which the Commission cannot endorse. Such a practice would be contrary to the values of equality and respect of human dignity to which the Commission fully subscribes.

In conclusion, given the complexity of the problematics and conflicting values to be conciliated, the Commission considers that access to PGD should not be offered to couples who from the outset seek to give birth to a child with a disability, while no restriction should be imposed on the genetic status of implanted embryos, once PGD has been performed.

417 John C. FLETCHER, "Sourd comme nous: le cas Duchesneau-McCullough", *L'Observatoire de la génétique*, July-August 2002, n° 5, [online], [http://www.ircm.qc.ca/bioethique/obsgenetique/cadrages/cadr2002/c\\_no5\\_02/c\\_no5\\_02\\_1.html](http://www.ircm.qc.ca/bioethique/obsgenetique/cadrages/cadr2002/c_no5_02/c_no5_02_1.html) and GOVERNEMENT OF CANADA, *Biostrategy*, [online], [http://biostrategy.gc.ca/HumanRights/HumanRightsE/ch3\\_6\\_f.html#\\_ftnref151](http://biostrategy.gc.ca/HumanRights/HumanRightsE/ch3_6_f.html#_ftnref151) (This page is no longer accessible. It seems to have been replaced by: <http://www.biportal.gc.ca/english/view.asp?x=520>).

418 Jacques PONCIN, *op. cit.* (our translation).

419 F. SHENFIELD *et al.*, "Taskforce 5: preimplantation genetic diagnosis", *Human Reproduction*, 2003, vol. 18, n° 649, p. 651.

## Sex selection

Some parents use PGD in order to choose the sex of the child when they are carriers of an X-linked disease, such as hemophilia,<sup>420</sup> which develops most often in boys and more rarely in girls. In such cases, sex selection is motivated by purely medical reasons. However, the Commission considers that the possibility of choosing the sex of a child for cultural, personal, or socio-economic reasons is an entirely different matter. For example, it seems that some couples would like to be able to select the sex of their embryos for the purposes of family balancing. In other words, parents could choose the sex of a second child to have one of each sex.<sup>421</sup>

There does not seem to be any consensus in this area among professional associations. The American College of Obstetricians and Gynecologists recommends not selecting the sex of the embryo through PGD, except for medical reasons.<sup>422</sup> The American Society for Reproductive Medicine (ASRM) considers that sex selection for non-medical reasons should not be encouraged.<sup>423</sup> It nevertheless believes that sorting sperm for purposes of family balancing is ethically acceptable if the method is safe and effective.<sup>424</sup> This openness is reflected in the fact US clinics offer this service. Indeed, over 80% of clinics offering PGD in the US practice sex selection for non-medical reasons.<sup>425</sup> It should however be noted that these clinics offer this service only to people undergoing PGD for medical reasons, and sex selection constitutes an additional option.

According to data collected by the PGD Consortium for 2004, for 45 centers around the world having performed a total of 3,530 PGD procedures, 104 cycles involved sex selection for sex-linked disease and 95 only for social reasons.<sup>426</sup>

## The choice of specific characteristics

The Commission wishes to raise the issue of selecting embryos with certain characteristics particularly favoured by prospective parents. This type of selection is sometimes referred to as production of “customized babies”, given the subjective nature of indications. The choice may involve physical traits such as height, eventual baldness, skin colour, eye or hair colour, as well as psychological or performance traits such as intelligence, musical, artistic or athletic capacity. Some people are even interested in the choice of sexual orientation and an article in the *Observatoire de la génétique* even mentions the possible identification of the “criminal gene.”<sup>427</sup> Science does not seem able to meet these expectations for the time being, but it is clear that some demand for the selection of genetic characteristics based on reasons of so-called convenience could develop in the future.

For the Commission, the conception of human dignity is undermined by the prospect of a world where parents choose the physical and psychological traits of their child. First, such a prospect reflects the instrumentalization of the unborn being. Although the child may be wanted for itself, the child would be conceived with particular determined physical and psychological traits valued by its parents and possibly by society. Thus, people might want the best for their child and, as a result, do everything possible to ensure the child's chances of personal, social and professional success. However well intentioned these wishes may be, they should not influence the selection of embryos for implantation after PGD. Such indications clearly depend on the parents' desire to select a child that will fulfill their desire.

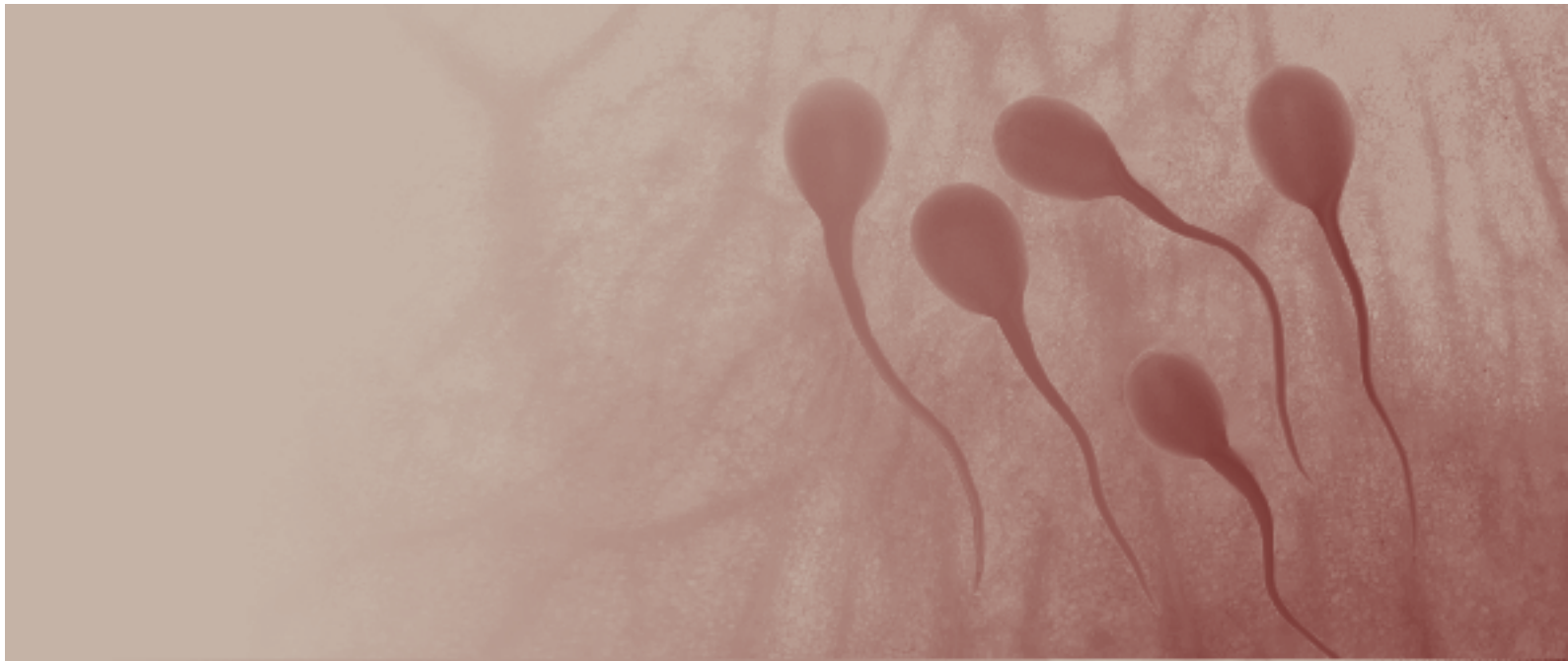
*Whereas preimplantation genetic diagnosis for non-medical reasons is unacceptable ethically, because it conflicts with respect for the symbolic freedom of the child, and opens the door to choices about specific characteristics that may not pose a risk to the health and well-being of children, but nevertheless would undermine human dignity, the Commission recommends:*

### Recommendation No. 19

That the use of preimplantation genetic diagnosis be prohibited for the production of “customized babies”, based on non-medical indications, *and that* the use of preimplantation genetic diagnosis be prohibited:

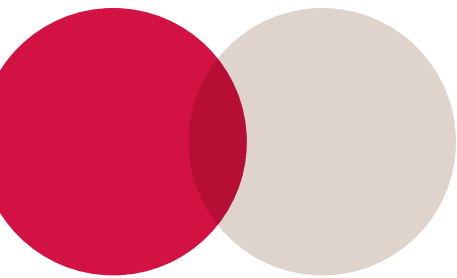
- When the goal is the deliberate production of a child with disabilities or handicaps;
- When sex selection of a child is based on cultural, religious, personal or socio-economic reasons.

- 420 See CANADIAN HEMOPHILIA SOCIETY, *Heredity of hemophilia*, [online], <http://www.hemophilia.ca/en/bleeding-disorders/hemophilia-a-and-b/heredity-of-hemophilia/>.
- 421 Julie COUSINEAU, *op. cit.*, p. 450.
- 422 AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS COMMITTEE ON ETHICS, *Sex Selection*, Committee opinion, n° 37, February 2007 (position reaffirmed in 2008).
- 423 AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE, “Preimplantation Genetic Testing: a Practice Committee Opinion”, *op. cit.*
- 424 ETHICS COMMITTEE OF THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, “Preconception gender selection for nonmedical reasons”, *Fertility and Sterility*, 2001, vol. 75, n° 5 (position reaffirmed in 2006).
- 425 Susannah BARUCH, “PGD: Genetic Testing of Embryos in the United States”, presentation to the European Commission, 15 February 2009.
- 426 ESHRE, *op. cit.*, p. 19.
- 427 Isabelle MONTPETIT, “Gènes et comportements: ce qu'en pense le Nuffield Council”, *L'Observatoire de la génétique*, November-December 2002, n° 8, [online], [http://www.ircm.qc.ca/bioethique/obsgenetique/zoom/zoom\\_02/z\\_no8\\_02/z\\_no8\\_02\\_3.html](http://www.ircm.qc.ca/bioethique/obsgenetique/zoom/zoom_02/z_no8_02/z_no8_02_3.html).





CONCLUSION



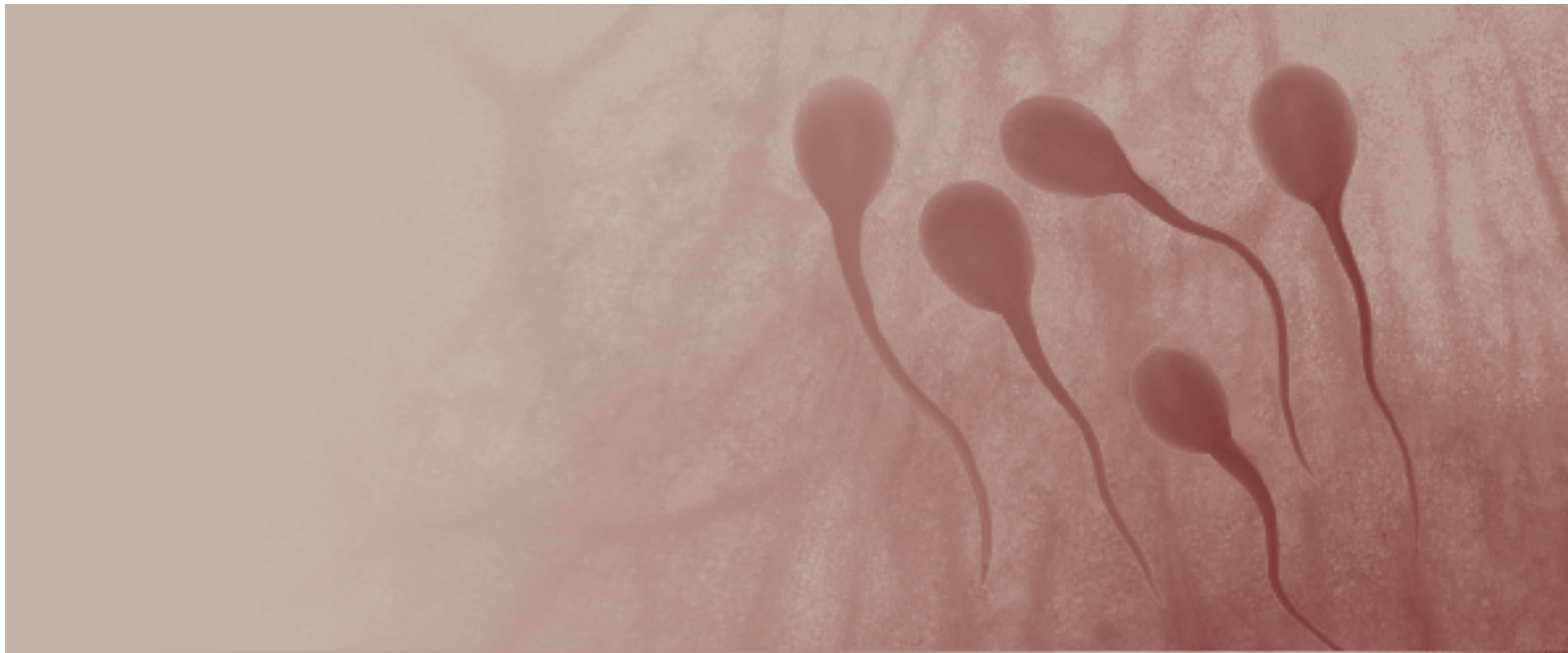
## CONCLUSION

In a society that values autonomy, freedom of choice, and that emphasizes individual rights, questioning the legitimacy of the requests that citizens make of the State can be a delicate matter. Even so, this is precisely what the Commission has had to do, in the present position statement, in fulfilment of the mandate entrusted to it. In the field of assisted procreation, the requests of infertile people or of those carrying genes for inherited genetic diseases are often perceived as distress signals. It should be noted that from the point of view of people articulating the desire to have children, this desire can easily become a fundamental need. While considering that having

children is a privilege rather than a right, the Commission expresses its empathy for people who encounter significant problems conceiving naturally, without medical assistance. However, as moving as the requests for medical assistance may be, they must also be acceptable in societal terms. This is why the Commission has drafted recommendations and is offering guidelines which in ethical terms serve the public welfare; not all recommendations or guidelines will meet with universal approval, but the line of argument offered by the Commission may nevertheless contribute to public debates.

In this position statement, the Commission makes nineteen recommendations for the donation of gametes and embryos in assisted procreation, surrogacy and preimplantation genetic diagnosis. Since it is important to know more about the outcomes of practice in order to respond appropriately in decision making, some recommendations focus on the medical follow-up needed for children resulting from AP and for people participating in AP procedures, and for monitoring children who underwent PGD at the embryonic stage. In terms of access to origins, and in addressing the inequality of rights between adopted children and children resulting from donated gametes, the Commission recommends applying the same practices as prevail in matters of adoption. Its reflection on the donation of gametes and embryos leads to six recommendations. Upstream of the practice of assisted procreation, the prevention of infertility is the subject of a three-part recommendation addressed directly to the Quebec government: the Commission proposes actions including an awareness campaign, socio-economic measures and public policies that promote the fulfilment of the parental project at an earlier age of adulthood than at present and research programs on the prevention of infertility. In terms of surrogacy, the Commission only makes one recommendation: that the principle of the nullity of contracts for surrogate motherhood be maintained, despite the risk that “procreative tourism” could develop further. The Commission concludes its analysis with preimplantation genetic diagnosis. As this practice is very new, and is situated at the frontier of care and innovation, the Commission devotes several recommendations to it, seven of which relate to access criteria. In this regard, the Commission has repeatedly come up against a problem that should be addressed by another mechanism of the State, namely the harmonization of criteria used to authorize access to prenatal diagnosis and preimplantation genetic diagnosis.

Each of the three issues discussed – gamete and embryo donation, surrogacy and preimplantation genetic diagnosis – could form the subject of a position statement on its own. Other issues would have profited from more detailed discussion, such as *in vitro* fertilization, prenatal diagnosis, eugenics and filiation, just to name a few. Moreover, the electronic public consultation the Commission undertook in the context of its review identified themes and ethical issues that respondents would like to see subjected to a thorough public debate in coming years: for example, the financing of assisted procreation, the risk of eugenics associated with embryo selection, the medicalization of procreation and the desire to have a biologically related child. The Commission hopes, however, that this position statement will contribute to advancing reflection which is now needed more than ever, and to inform the Quebec legislator on the matter.





## GLOSSARY



## GLOSSARY<sup>428</sup>

**ADRENOLEUKODYSTROPHY:** an X-linked genetic disease, which may begin in childhood, adolescence or adulthood. It is characterized by demyelination<sup>429</sup> of the central nervous system (brain and/or spinal cord) and adrenal insufficiency.<sup>430</sup>

**ALLELE:** Each of the different possible forms of the same gene. Alleles occupy the same locus on a pair of homologous chromosomes. They govern different aspects of the same character, whose expression depends on the relationship of dominant and recessive alleles.

**ALZHEIMER'S DISEASE:** "It is an irreversible disease of the brain in which the progressive degeneration of brain cells causes thinking ability and memory to deteriorate."<sup>431</sup>

**ANEUPLOIDY:** Aneuploidy is a change in the number of chromosomes. The development of embryos suffering from aneuploidy tends to cease in the first few days.<sup>432</sup> The number of chromosomes may be insufficient (monosomy) or excessive (trisomy).

**ARTIFICIAL INSEMINATION (AI):** Assisted reproductive technique which consists in injecting sperm into the uterus without sexual intercourse. AI can be broken down into three main categories: self-insemination, insemination performed in a clinic with the spouse's sperm or with donor sperm, and intrauterine insemination. (OQLF and CEST)

**ASSISTED HATCHING:** Technique enabling an embryo transferred into the uterus of a surrogate to emerge from the pellucid zone (the outer shell around the embryo) to facilitate implantation for pregnancy. (CEST)

**ASSISTED PROCREATION (AP):** A set of techniques facilitating procreation outside of the natural reproductive process, or involved in the conception of healthy children in a context of possible parental transmission of serious illness, whether genetic or viral. (CEST, based on OQLF)

**CARRIER EMBRYO:** An embryo having two distinct alleles on a given locus from the same pair of chromosomes. Also known as *heterozygous embryo*. (CEST, based on OLF)

**CHROMOSOMAL TRANSLOCATION:** Chromosomal abnormality in which a fragment of a chromosome is broken off and attached to a non-homologous chromosome.

**CRYOPRESERVATION:** A means of conserving embryos by freezing them in liquid nitrogen. It is also possible to store sperm in this way. Sperm can be conserved indefinitely in this fashion, while at room temperature fresh semen can only be conserved for a few hours.

**CYSTIC FIBROSIS (OR MUCOVISCIDOSIS):** An inherited autosomal recessive disease characterized by the overproduction of highly viscous mucus that blocks the ducts of affected organs and may predispose the subject to life-threatening respiratory infections.



**DESIGNER BABY:** A child conceived in order to heal sick siblings. Preimplantation genetic diagnosis is used to select a healthy embryo compatible with the sick sibling. About one in five embryos is healthy and compatible. This treatment is used to treat leukemia (blood cancer) and Fanconi anemia, a genetic disease appearing after the age of six. For both diseases, the treatment consists in transplanting umbilical stem cells from the other child. In order to heal the sick child, the designer baby may become a donor not only of cord blood, but also of bone marrow, on one or more occasions in the event of complications. Also known as *saviour child*. (CEST)

**DOMINANT:** Pertaining to a trait that is expressed in both homozygous and heterozygous individuals, i.e. when either or both homologous alleles of a gene code for a trait. (CEST, based on OQLF)

**DUCHENNE MUSCULAR DYSTROPHY:** A recessive genetic X-linked disease. It affects all muscles of the body. Around the age of 10 or 12 years, walking becomes impossible and the use of upper limbs becomes increasingly difficult.<sup>433</sup>

**EGG DONOR:** A woman who agrees to give her eggs to another woman so the latter can have a child. (CEST)

**EMBRYO:** The product of conception during approximately the first three months of pregnancy, that is, until the egg is released from the vitelline envelopes.

**EPIGENETIC:** Characterizes a process in which intracellular elements or membrane assemblies and recombinations may modify the hereditary component of a cell in ways outside of to the laws of genetics.

**ETHICAL ISSUE:** The notion of an issue means first of all that things are at stake, that something important is playing out in a situation that challenges those experiencing it. An ethical issue brings into a state of tension the actions, rules, values or elements of a store of meaning that drive a person or group of persons. This state of tension may result from practices, rules, values or perceptions that compete in a decision-making process or an intervention.<sup>434</sup>

**EUGENICS:** A science that examines and seeks to implement the conditions most favourable to the improvement of the hereditary traits of human populations, particularly with a view to eliminating hereditary diseases.

- 428 Unless otherwise indicated, definitions in this glossary are drawn from *Le grand dictionnaire terminologique* of the OFFICE QUÉBÉCOIS DE LA LANGUE FRANÇAISE (OQLF).
- 429 Destructive removal of the myelin sheath enveloping the nerve. (VULGARIS MÉDICAL, *Démyélinisation Remyélinisation*, [online], <http://www.vulgaris-medical.com/encyclopedie/demyelinisation-remyelination-temps-de-1388.html>).
- 430 Adrenal insufficiency results from an inadequate production of certain hormones in the adrenal glands. (INTÉGRASCOL, *L'insuffisance surrénale*, [online], <http://www.integrascal.fr/fichemaladie.php?id=19>; ASSOCIATION EUROPÉENNE CONTRE LES LEUCODYSTROPHIES (ELA), *L'adrénoleucodystrophie*, [online], <http://www.ela-asso.com/?q=node/957>).
- 431 ALZHEIMER SOCIETY, *op. cit.*
- 432 IVF ZENTREN PROF. ZECH, *Cultivation of the embryo up to the blastocyst stage*, [online], <http://www.ivf.at/KultivierungVonEmbryonenBlastozystenStadium/tabid/124/language/en-US/Default.aspx>.
- 433 Tuy Nga BRIGNOL, *Dystrophie musculaire de Duchenne*, Association française contre les myopathies, June 2006, [online], [http://www.afm-france.org/ewb\\_pages/fj\\_fiche\\_maladie\\_Dystrophie\\_musculaire\\_de\\_Duchenne.php](http://www.afm-france.org/ewb_pages/fj_fiche_maladie_Dystrophie_musculaire_de_Duchenne.php).
- 434 Pierre FORTIN and Pierre-Paul PARENT, *Le souci éthique dans les pratiques professionnelles – Guide de formation*, Paris, l'Harmattan, 2004, p. 91.

**FERTILIZATION:** The union of the nucleus and other cellular components of a male gamete (sperm) and a female gamete (ovum) which results in the fertilized egg or zygote, from which a new individual may grow.

**FETUS:** The name given to the product of conception after the third month of uterine life, in other words from around the time when it begins to exhibit the distinctive characteristics of humans.

**GAMETE:** A differentiated haploid reproductive cell, resulting from meiosis, which can fuse with a similar cell from a member of the opposite sex through the process of fertilization, in order to procreate a diploid zygote, or new individual in the animal (metazoan) kingdom. In humans, gametes are called “sperm” (male) and “egg” or “ovum” (female).

**GENOTYPE:** All the genetic material carried by an individual which constitutes his hereditary material.

**GONADOTROPIN:** A group of hormones that stimulate the hormonal secretion of genital glands: ovaries or testes.

**GRAAFIAN FOLLICLE:** An ovarian follicle which has reached maturity, and will then break on the 14<sup>th</sup> day of the cycle (ovulation), expelling the egg into the Fallopian tube.

**HEMOPHILIA:** An X-linked recessive hereditary disorder, transmitted only by women, affecting only males, and characterized by a delay in, or total lack of, blood clotting as well as a tendency to hemorrhage.

**HETEROZYGOUS (OR HETEROZYGOTE):** A cell or individual having two distinct alleles at a particular locus on the same pair of chromosomes.

**HLA SYSTEM:** An immune complex involved in transplant rejection. This system includes four genes HLA-A, B, C and D located on chromosome 6. The genes A, B, C code for well-defined proteins located on the membranes of all body cells, which are used primarily for self-recognition. [...] The HLA system is extremely useful not only for the choice of grafts, but also for investigating susceptibility to certain diseases.

**HOMOZYGOUS:** A cell or individual having two identical alleles (normal or pathological) at a particular locus on the same pair of chromosomes.

**HUNTER SYNDROME:** An X-linked genetic disease, which affects mostly boys. It is also known as *Mucopolysaccharidosis II* (MPS II) and is characterized by dwarfism, mental retardation, deafness and frequent respiratory infections.<sup>435</sup>

**HYSTERECTOMY:** The surgical removal of part or all of the uterus.

**INFERTILITY:** The inability or difficulty of a person or couple to have children naturally. Definitions vary, some of them including a time factor. For example, the WHO speaks of infertility as the inability to conceive after a year of unprotected intercourse. (CEST)

**IMMUNOGENETIC COMPATIBILITY (OR TYPING) (OR HLA):** The greater or lesser biological similarity of donor tissues with those of the recipient. From a biological standpoint, every human being is defined by antigens in tissue groups particular to that human being. HLA (Human Leucocyte Antigen) is essential [...]. One can speak of immunogenetic compatibility when donor tissue has the same HLA as the recipient or a closely related group. Otherwise, graft rejection and therefore graft failure will ensue.<sup>436</sup>

**INTRACYTOPLASMIC SPERM INJECTION (ICSI):** A technique during an IVF process which involves injecting a single sperm through the outer shell around the egg, using a micropipette. Fertilization and cell division follow. This technique is necessary when male infertility is sufficiently severe to prevent the sperm from penetrating the egg envelope. (CEST)

**IN VITRO:** Refers to a fact, experience or reaction occurring in an artificial environment, in the laboratory on a glass slide or in laboratory glassware.

**IN VITRO FERTILIZATION (IVF):** The fusion of egg and sperm performed outside the body, in a glass jar in the laboratory.

**IN VITRO MATURATION (IVM):** A new fertilization technique enabling the *in vitro* maturation of immature oocytes. Unlike IVF, this approach does not require hormone therapy (ovarian stimulation). (OQLF and CEST)

**IN VIVO:** Refers to a fact which is evolving, or to an experience or exploration which is observed or practiced in a living organism.

**KARYOTYPE:** The characteristic chromosomal makeup of an organism, defined by the size, shape and number of chromosomes.

**LEUKEMIA:** The malignant clonal proliferation of one or more cell lines from hematopoietic stem cells located in bone marrow and often characterized by leukocytosis. Synonym: *blood cancer*.

**MEDICAL INDICATIONS:** A set of elements observed leading to a therapeutic decision.

**MEDICALIZATION OF REPRODUCTION:** The application of medical techniques to the conception of children, such as artificial insemination and *in vitro* fertilization. (CEST)

**MYOTONIC DYSTROPHY (OR STEINERT'S DISEASE):** A dominant genetic disease characterized by myotonia (a sensation of stiffness due to the difficulty of muscular relaxation after movement) and dystrophy (the atrophy and progressive loss of muscle strength). [...] The course of this disease varies greatly among individuals; it is sometimes benign and sometimes causes serious disability (loss of the ability to walk after 15 to 20 years and cognitive difficulties).<sup>437</sup>

**NON-DISCLOSURE DIAGNOSIS:** A type of diagnosis undertaken in the case of late-onset diseases (Huntington's disease, for example) when the prospective parents do not want to know their genetic status. The medical team agrees to transfer only healthy embryos and not to disclose test results to the applicant couple. (CEST)

**OOCYTE:** A female sex cell undergoing development, located on the ovarian parenchyma. The oocyte develops into a fertilizable ovum over different timeframes, depending on the species.

**OVARIAN HYPERSTIMULATION SYNDROME (OHSS):** Complications arising from the treatment of ovarian stimulation, due to the production of too many eggs. (CEST)

**OVARIAN STIMULATION (OS):** Part of IVF, this hormonal treatment takes place during the pre-ovulatory phase, and is intended to bring about the simultaneous growth of several follicles.

**OVARY:** The paired and symmetrical female genital gland, which has a dual function: the sexual function of egg maturation and expulsion, and a related hormonal function consisting in secreting estrogen and progesterone in regulating the menstrual cycle.

**OVULATION:** The rupture of a mature Graafian follicle, releasing an ovum which is now suitable for fusion with sperm.

**PHENOTYPE:** All observable (morphological or functional) characteristics corresponding to the expressed part of the genotype and to external factors.

**POLYMERASE CHAIN REACTION (PCR):** A technique to amplify enzymes *in vitro* and to make multiple copies of a short RNA or DNA sequence.

435 ENCyclopédie UNIVERSALIS, *Maladie de Hunter*, [online], [http://www.universalis.fr/encyclopedie/EB06463/MALADIE\\_DE\\_HUNTER.htm](http://www.universalis.fr/encyclopedie/EB06463/MALADIE_DE_HUNTER.htm).

436 MINISTÈRE DE LA SANTÉ, DE LA JEUNESSE, DES SPORTS ET DE LA VIE ASSOCIATIVE, "Dons d'organes, de tissus et de cellules", *Les dons d'organes et de sang*, [online], <http://www.sante.gouv.fr/htm/pointsur/dons/612.htm>.

437 Tuy Nga BRIGNOL, *Dystrophie myotonique de Steinert*, Association française contre les myopathies, June 2006, [online], [http://www.afm-france.org/ewb\\_pages/f/fiche\\_maladie\\_dystrophie\\_myotonique\\_de\\_steiner.php](http://www.afm-france.org/ewb_pages/f/fiche_maladie_dystrophie_myotonique_de_steiner.php).

**PREIMPLANTATION GENETIC DIAGNOSIS (PGD):** A diagnostic technique practiced in the context of *in vitro* fertilization – but not necessarily in a context of infertility – to diagnose certain diseases before the embryo is implanted in the uterus of a surrogate mother. Shortly after fertilization, one or two cells are removed from the embryo for genetic analysis, in order to verify whether the cells carry a particular genetic abnormality or abnormalities. This technique can also be used in the selection of embryos that will in turn become designer babies. (CEST)

**PRENATAL DIAGNOSIS (PND):** Detection in the fetus of abnormalities or malformations making it possible to establish an accurate diagnosis of a serious or fatal genetic disease.

**RECESSIVE:** Refers to a gene that only produces its effect when it is present on each of the two homologous chromosomes.

**REIFICATION:** A mental operation consisting in transforming abstract concepts into concrete realities or objects.

**SELF-ELECTED FAMILY:** Refers to a family whose members have “chosen” one another and whose filiation is based on emotional ties, unlike the so-called “biological family.” The adoptive family is an example of a family choice. (CEST)

**SEX-LINKED DISEASE:** There are many X-linked genetic diseases. These diseases involve the presence of a defective allele of a gene located on an X-specific site. In the case of recessive diseases, we only speak in general of boys being affected, even going so far as to say ‘girls are not affected.’ This is generally not true, however. [...] The simple fact is that very few girls are affected because of the rarity of the disease: with an incidence of 1/10,000, it is indeed very unlikely that a man with hemophilia will have children with a woman who also carries the mutant allele.<sup>438</sup> Also known as *X-linked disease*.

**SICKLE CELL ANEMIA:** A form of chronic hereditary anemia. It is characterized for example by vulnerability to infections and painful crises that typically arise in the limbs, abdomen, back, chest and sometimes the bones.<sup>439</sup>

**SPARE EMBRYOS:** Embryos obtained through *in vitro* fertilization, but which cannot immediately be implanted in the uterus. Also known as *supernumerary* or *surplus embryos*.

**SPERM DONOR:** A man who agrees to donate his sperm to allow a single woman or a couple to have a child. (CEST)

**SPINAL MUSCULAR ATROPHY:** A group of inherited disorders characterized by weakness and atrophy of muscles. They attack the nerve cells (motoneurons) that stimulate and control the voluntary muscles, causing them to deteriorate. There are three forms of spinal muscular atrophy: infantile spinal muscular atrophy (type-I), intermediate spinal muscular atrophy (type-II) and juvenile spinal muscular atrophy (type-III).<sup>440</sup>

**STEINERT’S DISEASE:** See *Myotonic dystrophy*.

**STEM CELL:** An undifferentiated cell, derived from the embryo, fetus or adult tissues, which has both the ability to multiply by successive divisions for an indefinite period and also to give rise, under specified conditions, to one or more lines of differentiated cellular elements. Stem cells can also be extracted from umbilical cord blood. (OQLF and CEST)

**SURROGACY (OR SURROGATE MOTHERHOOD):** The fact that a woman agrees to become pregnant and to deliver a child for another person or a couple. A number of other terms also apply to surrogacy, such as “pregnancy contract”, “surrogate mother” and “womb for rent”. In this position statement, the term “traditional surrogate” is used when a woman (a third party) is inseminated with her own eggs which have been fertilized by spouse’s sperm from the couple; the term “gestational surrogate” is used when a woman is inseminated with fertilized eggs from another woman; in a generic sense, the term “surrogate” is used. (CEST)

**SURROGATE MOTHER:** See *Surrogacy*.

**SUSCEPTIBILITY (OR GENETIC) PREDISPOSITION**

**(OR SUSCEPTIBILITY GENES):** The possibility that a person may suffer from a specific disease during his life, whether because of a gene or from a still poorly known combination of several genes and environmental factors, such as diet and other lifestyle habits. (CEST)

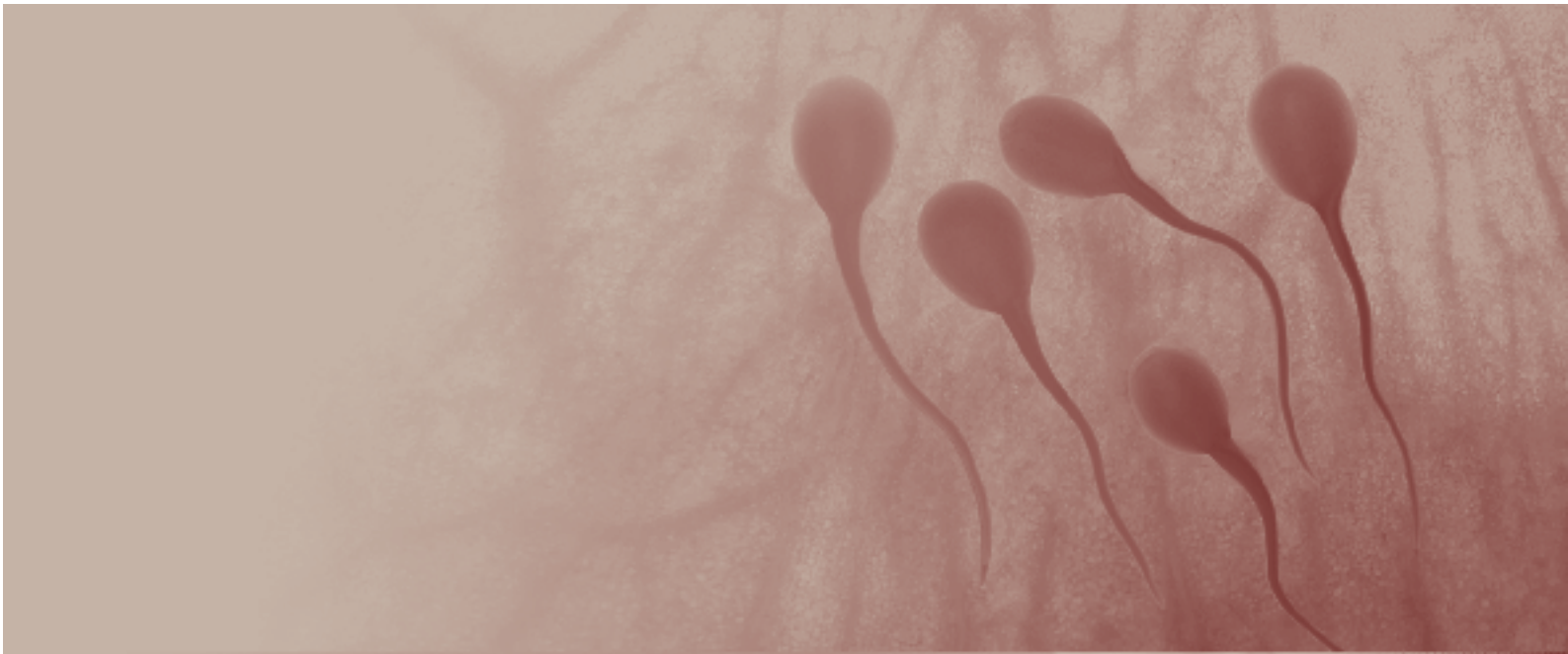
**THIRD-PARTY CONTRIBUTION TO THE PARENTAL PROJECT:**

The involvement of a third party (or even a couple) in the conception of a child, whether through sperm or egg donation, surrogacy or embryo donation. (CEST)

**TISSUE TYPING:** The identification of histocompatibility antigens, or HLA antigens (Human Leucocyte Antigens), genetically transmitted and expressed in the cells of an individual and characterizing his tissue group. See *Immunogenetic compatibility (or typing) (or HLA)*.

**X-LINKED DISEASE:** See *Sex-linked disease*.

- 438 A. LAFLEUR, *Femmes et maladies liées au sexe*, [online], <http://www.snv.jussieu.fr/vie/faq/ts/faqs.htm#xhemo>.
- 439 Robert DEHIN and Jocelyne AUBRY, *Anémie à hématies falciformes*, Passeportsanté.net, [online], [http://www.passeportsante.net/fr/Maux/Problemes/Fiche.aspx?doc=anemie\\_falciforme\\_pm#P43\\_7583](http://www.passeportsante.net/fr/Maux/Problemes/Fiche.aspx?doc=anemie_falciforme_pm#P43_7583).
- 440 PORTAIL INFORMATION HOSPITALIÈRE, *L'actualité hospitalière et médicale en ligne. Dictionnaires santé*, [online], <http://www.informationhospitaliere.com/dico-249-amyotrophie-spinale.html>.





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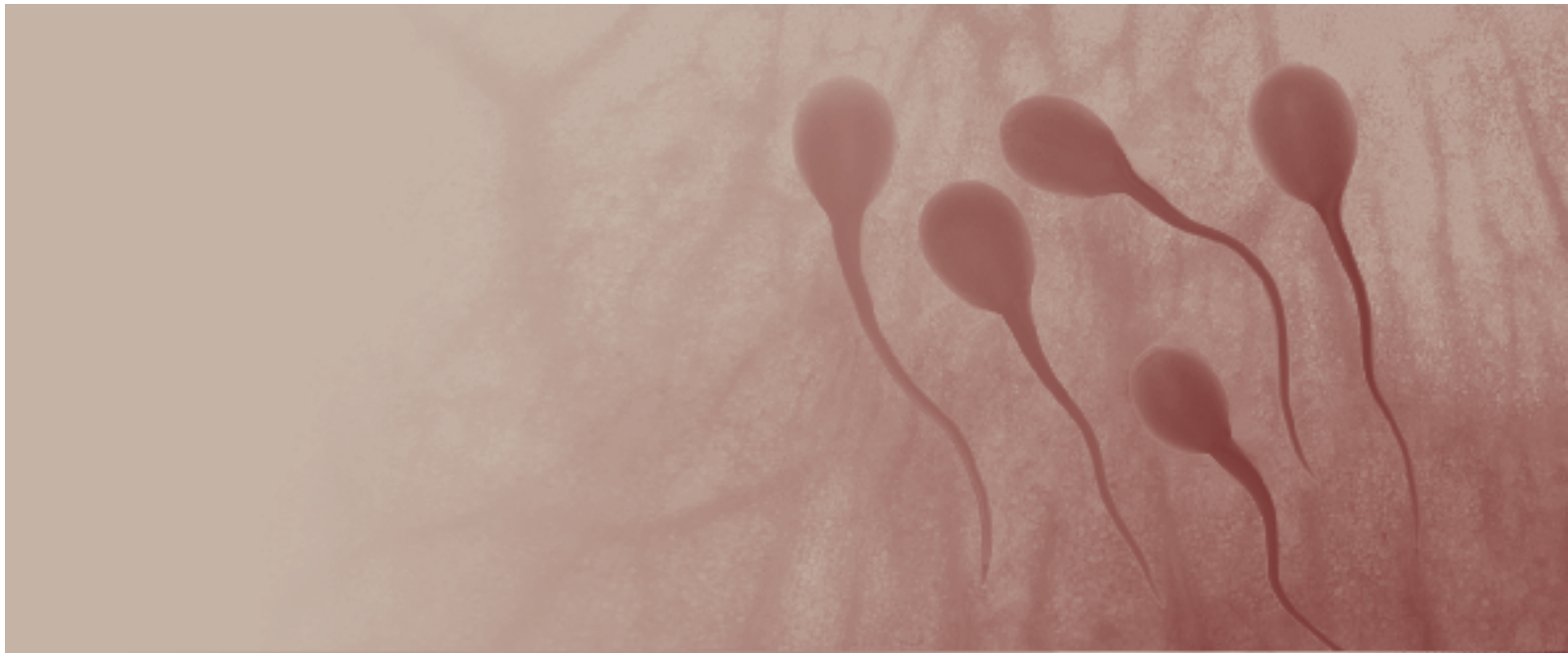
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APPENDICES

## SEMEN DONOR RECRUITMENT, SCREENING AND TESTING

### 1. DONOR SELECTION - GENERAL

#### 1.1 Recruitment

Any healthy men not excluded on the basis of the criteria set out under the heading “Exclusions” in Clause 2 are eligible to donate semen.

#### 1.2 Donor Screening Procedures

Each semen bank or fertility clinic shall adhere to donor screening procedures as specified in the facility’s Standard Operating Procedures (SOPs) and this directive.

#### 1.3 Medical Records

Medical records regarding the donor should be kept indefinitely.

### 2. EXCLUSIONS

#### 2.1 Exclusion criteria

The exclusion criteria shall include the following:

- a. Employment by the facility or having a family member employed by the facility;
- b. Age greater than 40 years;
- c. Indications of high risk for the Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), or Human T-cell Lymphotropic Virus (HTLV), including:
  - i. men who have had sex with another man, even once, since 1977;
  - ii. persons who report intravenous, intramuscular, or subcutaneous injection of drugs that are not prescribed by a licensed physician for medical purposes;

- iii. persons who report tattoos or body piercing involving non-sterile skin penetration in the preceding 12 months;
- iv. persons with hemophilia or related clotting disorder who have received human derived clotting factor concentrates;
- v. persons who have engaged in sex in exchange for money or drugs at anytime since 1977;
- vi. persons who have had sex in the preceding 12 months with any person described in item (c)(i) through (c)(v) above;
- vii. persons who have been exposed to known or suspected HIV infected blood or body fluids through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane;
- viii. persons who cannot be tested for infectious disease agents because of refusal, inadequate blood sample, or other reasons;
- ix. persons with a history of repeatedly reactive screening for antibody to HIV-1 or HIV-2, Hepatitis B surface antigen (HBsAg), antibody to Hepatitis B core (HBc) antigen, antibody to HCV, or antibody to HTLV-I or HTLV-II, regardless of the results of supplemental assays;
- x. persons whose history, physical examination, medical records, or pathology report reveal other evidence of infection or high-risk behaviours, such as:
  1. diagnosis with Acquired Immuno-Deficiency Syndrome (AIDS);
  2. unexplained weight-loss;
  3. night sweats;
  4. blue or purple spots on the skin or mucous membranes typical of Kaposi's Sarcoma;
  5. unexplained lymphadenopathy lasting more than 1 month;
  6. unexplained temperature greater than 38.6 °C (100.5 °F) for more than 10 days;
  7. unexplained persistent diarrhea; or
  8. needle tracks or other signs of parenteral drug use;
- xi. persons who have, or have had, sex with a person known to have HIV, HBV, HCV, or HTLV infection, or who is at high risk for such infection;

- xii. persons who are at risk of having acquired HIV from geographic regions which are endemic for HIV strains that are not detectable by current screening tests (these individuals may be reconsidered once tests to detect the variant strains become available);

**Note:** Information regarding geographic regions which are endemic for HIV strains that are not detectable by current screening tests is available at Health Canada;

- xiii. persons with active viral hepatitis;
- xiv. persons who have received, or whose sexual partners have received blood, blood components, blood products or other human tissues in the preceding 12 months;
- xv. persons who have been exposed to blood or body fluids through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane in the preceding 12 months;
- xvi. persons who have been excluded permanently from donating blood;
- xvii. persons who have used intra-nasal cocaine in the preceding 12 months;

**Note:** The criteria outlined in clause 2.1(c) have been excerpted from the Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs - Morbidity and Mortality Weekly Report (MMWR), US Center for Disease Control: 43; RR8, May 29, 1994, and modified to conform with the exclusion criteria for Canadian blood donors.

- d. Sexually transmitted disease in the preceding 12 months;
- e. Sexual encounter in the preceding 12 months with someone whose sexual background the potential donor is unsure of;
- f. Urethral discharge, genital warts, or genital ulcers at the time of donation;
- g. History of alcoholism;
- h. Diagnosis with Creutzfeldt-Jakob Disease (CJD) or a first degree family member with a history of CJD;
- i. Receipt of human pituitary-derived growth hormone or dura mater;
- j. Spongiform encephalopathy or prion disease;
- k. Viral encephalitis or encephalitis of unknown origin; or
- l. Any major systemic diseases, including systemic malignancies.

## **2.2 Semen Processed Prior to March 14, 2000**

For semen processed prior to March 14, 2000, only the measures set out in Clause 6 apply.

## **3. WORK-UP**

### **3.1 Suitability of donor**

The suitability of a specific individual for semen donation shall be documented and based on medical, sexual and social history, clinical status, physical examination, and laboratory test results.

### 3.2 Questionnaire

The Medical Director or a Physician Designated by the Medical Director shall be responsible for the preparation of medical, social and sexual history questionnaires.

### 3.3 Processus de sélection des donneurs

#### 3.3.1 Donor Information Sheet

A donor information sheet should be provided to the donor.

#### 3.3.2 Required Elements

- a. The donor selection process shall include the following:
  - i. staff designated by the Medical Director of the semen bank or fertility clinic shall have initial discussions with the potential donor. The discussion shall emphasize the importance of the Donor Insemination (DI) Programmes and the donors' responsibilities towards them;
  - ii. a donor consent form shall be completed by the donor; and
  - iii. a donor medical questionnaire must be completed.
- b. A preliminary semen evaluation, including a cryopreservation test, shall be conducted.
- c. A medical interview shall be conducted, and shall include:
  - i. a physical examination;
  - ii. a medical history; and
  - iii. laboratory tests, including the infectious disease tests specified in Clauses 3.5.2 and 3.5.4. The infectious disease tests specified in Clause 3.5.3 should also be performed.
- d. The acceptance of a donor shall be decided by the Medical Director or a Physician Designated by the Medical Director.
- e. If a donor is accepted, a unique identifier shall be assigned to that donor. The semen bank or fertility clinic shall be responsible for ensuring donor confidentiality.

### 3.4 Documentation

Documentation in respect of each donor shall include the following:

- f. Name of the donor;
- g. Unique identifier of the donor;
- h. Address of the donor;
- i. Donor's date of birth;
- j. Completed medical questionnaire;
- k. Completed donor consent form;
- l. Medical records;
- m. Completed physical examination results;
- n. Laboratory test results; and
- o. Name and signature of the Medical Director or a Physician Designated by the Medical Director, who reviewed, examined and approved the semen donor.

### 3.5 Initial Testing

#### 3.5.1 General

##### *3.5.1.1 Infectious disease testing*

- a. The Standard Operating Procedures (SOPs) of every semen bank or fertility clinic shall describe all infectious disease tests that must be performed.
- b. Testing shall be performed by a laboratory that meets federal accreditation requirements, or the accreditation requirements of the province or territory in which the laboratory is located, or in the case of imported semen, by a laboratory that meets a recognized equivalent accreditation requirement.
- c. The serological tests specified in Clause 3.5.2 shall be performed on a blood specimen obtained from the semen donor:
  - i. with donor screening test kits approved or licensed under the Canadian Medical Devices Regulations, if such test kits are available through the accredited laboratory referred to in Clause 3.5.1.1(b), or
  - ii. with diagnostic test kits that have been approved or licensed under the Canadian Medical Devices Regulations, in any other case.

**Note:** It is appropriate risk management to use diagnostic test kits on a temporary basis until donor screening tests are available and licensed under the Canadian Medical Devices Regulations.
- d. The serological tests specified in Clause 3.5.3 should be performed on a blood specimen obtained from the semen donor:
  - i. with donor screening test kits approved or licensed under the Canadian Medical Devices Regulations, if such test kits are available through the accredited laboratory referred to in Clause 3.5.1.1(b), or
  - ii. with diagnostic test kits that have been approved or licensed under the Canadian Medical Devices Regulations, in any other case.
- e. Microbiological testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* shall be performed with test kits that have been approved or licensed under the Canadian Medical Devices Regulations for the specimen being tested, if such test kits are available through the accredited laboratory specified in Clause 3.5.1.1 (b). The manufacturers' instructions for the performance and interpretation of their tests and the manufacturers' requirements for specimens shall be followed.
- f. If microbiological testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* is performed using a test or method developed by the accredited laboratory specified in Clause 3.5.1.1(b), the laboratory must have validation data to support the use of the test or method for the intended application.
- g. Donors who test positive for any of the infectious disease markers or infectious agents listed in Clauses 3.5.2, 3.5.4, 4.1.1, 4.2.2 (b), 5.1 and 5.2 must be rejected.

### 3.5.1.2 Notification Requirement

Positive results for the serological and microbiological tests specified in Clauses 3.5, 4 and 5 shall be immediately reported in writing to the donor by the semen bank or fertility clinic.

**Note:** Canadian semen processors should also report positive serological and microbiological test results to the Public Health Authority as required in the notifiable diseases reporting process under the applicable Public Health Act and Regulations of each province and territory.

### 3.5.2 Minimum Serological Testing

Minimum serological testing shall include tests for:

- a. Antibody to HIV-1 and 2;
- b. Antibody to HCV;
- c. Hepatitis B surface antigen (HBsAg);
- d. Antibody to Hepatitis B core antigen (IgG anti-HBcAg);
- e. Antibody to HTLV-I and HTLV-II; and
- f. *Treponema pallidum* (syphilis)
  - i. non-treponemal test; and
  - ii. treponemal-specific test (FTA-ABS or MHA-TP).

**Note:** Additional information on the laboratory diagnosis of syphilis can be found in the Canadian STD.

### 3.5.3 Additional Serological Testing

Additional serological testing should include tests for Cytomegalovirus (CMV) IgM & IgG.

**Note:** IgM positive donors should be deferred from donating semen until they become IgM negative. CMV IgG positive donors should also be deferred if any additional testing shows the presence of active infection at the time of donation. CMV IgG positive donors should be used only for CMV seropositive recipients. IgG negative donors may be used for CMV seropositive or seronegative recipients.

### 3.5.4 Minimum Microbiological Testing

Minimum microbiological testing shall include:

- a. A test for *Chlamydia trachomatis* using a nucleic acid amplification test on urine, urethral or semen specimens;
- b. A test for *Neisseria gonorrhoeae* using:
  - i. urethral or semen cultures; or
  - ii. a nucleic acid amplification test on urine, urethral or semen specimens; and

**Note:** Urine and urethral specimens for microbiological testing should be collected and transported as described in the Canadian STD Guidelines.

For the purposes of donor counseling and treatment, a positive nucleic acid amplification test result should be confirmed using a different set of primers to rule out false positive results. Additional information on the laboratory diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections can be found in the Canadian STD Guidelines.

c. A general semen culture and sensitivity evaluation.

**Note:** A positive test consists of any organisms not considered normal flora.

### 3.6 Rh Status

The donor's Rh Status shall be determined at either the initial testing stage, or at any time before the semen is released for distribution.

**Note:** In the case of an Rh negative recipient an Rh negative donor should be used whenever possible.

### 3.7 Archived Serum Samples

A serum sample should be collected from the donor and cryopreserved for retrospective testing when new tests are adopted for donor screening.

### 3.8 Semen Processed Prior to March 14, 2000

For semen processed prior to March 14, 2000, only the measures set out in Clause 6 apply.

## 4. REPEAT SCREENING AND QUARANTINE

### 4.1 Repeat Screening

#### 4.1.1 Serological Testing

The minimum serological tests outlined in Clause 3.5.2 should be repeated on new specimens obtained from the donor at least every 180 days while the donor remains an active participant in the program, and after interruptions exceeding 180 days.

#### 4.1.2 Cytomegalovirus (CMV) IgM & IgG.

a. Donors who tested positive for CMV IgG at the "Work-up" stage need not be retested for CMV IgG.

**Note:** If other tests show the presence of active infection in a CMV IgG positive donor, the donor should be deferred until the infection is resolved.

b. Donors who tested negative for CMV IgG or CMV IgM at the "Work-up" stage should be retested every 180 days to detect seroconversion in the donor.

**Note:** Seroconversion from a negative to positive IgG or IgM status on retest implies an infection occurred shortly before the donor was recruited or during the testing interval, and semen donated during this period should be discarded.

#### 4.1.3 Microbiological Testing

Repeat microbiological testing shall be performed at the time of each donation, as specified in Clause 5.

#### 4.1.4 Physical Examination

A physical examination of the donor should be conducted at least every 365 days while the donor remains an active participant in the program, and after interruptions exceeding 365 days.

### 4.2 Quarantine and Repeat Screening

#### 4.2.1 Quarantine Period

Fresh semen shall not be used for donor insemination. All donated semen must be frozen and quarantined for a minimum of 180 days.

**Note:** The quarantine period is to allow for the detection of seroconversion in the donor.

#### 4.2.2 Repeat Screening Prior to Distribution

After the semen donation has been quarantined for a minimum of 180 days but before it is distributed,

- a. The donor must be re-evaluated on the basis of the exclusion criteria and still found not to be within a group set out under the heading “Exclusions” in Clause 2;
- b. The minimum serological testing set out in Clause 3.5.2, with the exception of 3.5.2(c), must be repeated on a new specimen obtained from the donor; and
- c. Serological testing for CMV IgG and CMV IgM should be repeated where the donor tested CMV IgG or CMV IgM negative at the “Work-up” stage, using a new specimen obtained from the donor.

### 4.3 Evaluation of Semen Safety

#### 4.3.1 Role of the Medical Director or Physician Designated by the Medical Director

The Medical Director, who is responsible for the overall medical care, or his or her Physician Designate, shall determine and document whether semen may be released for distribution following a review of:

- a. Screening based on the exclusion criteria set out under the heading “Exclusions” in Clause 2;
- b. Donor infectious disease screening by serological and microbiological testing performed during the “Work-up” stage, as required under Clauses 3.5.2 and 3.5.4;
- c. Donor infectious disease screening by serological testing performed during the repeat testing, as required under Clause 4.2; and
- d. Microbiological testing performed as set out in Clauses 5.1 and 5.2.

#### 4.3.2 Semen Release

Evaluation of the safety of the tested semen shall be confirmed prior to the semen being released for distribution.

### 4.4 Semen Processed Prior to March 14, 2000

For semen processed prior to March 14, 2000, only the measures set out in Clause 6 apply.

## 5. MICROBIOLOGIE

### 5.1 Chlamydia trachomatis and Neisseria gonorrhoeae

A specimen collected from the donor at the time of each donation shall be tested for Chlamydia trachomatis and Neisseria gonorrhoeae as specified in Clauses 3.5.4 (a) and (b).

### 5.2 General Culture and Sensitivity Evaluation

Semen cultures for each donation shall include a general culture and sensitivity evaluation.

**Note:** A positive test consists of any organisms not considered normal flora.

### 5.3 Antibiotics

If antibiotics are included in the cryoprotectant medium formulation, it should be documented because of possible antibiotic sensitivity or allergy in recipients.

### 5.4 Semen Processed Prior to March 14, 2000

For semen processed prior to March 14, 2000, only the measures set out in Clause 6 apply.

## 6. SPERM PROCESSED PRIOR TO MARCH 14, 2000

### 6.1 Exclusion Criteria

- a. For semen fully processed prior to March 14, 2000, the criteria set out under the heading “Exclusions” of the CFAS 1996 Guidelines or those set out in Clause 2.1 of this Directive must have been applied.
- b. If, prior to March 14, 2000, semen has been collected but the repeat screening after a minimum quarantine period of 180 days has not been done, the repeat screening must be done in accordance with the criteria set out under Clause 2.1.

### 6.2 Serological Testing

#### 6.2.1 Work-Up

For semen processed prior to March 14, 2000, the following minimum serological tests must have been performed at the “Work-up” stage:

- a. Antibody to HIV-1 and 2;
- b. Antibody to HCV;
- c. Hepatitis B surface antigen (HBsAg);
- d. Antibody to HTLV I and II; and
- e. Treponema pallidum (syphilis) using
  - i. non-treponemal test; or
  - ii. treponemal-specific test (FTA-ABS or MHA-TP).

## 6.2.2 Repeat Screening and Quarantine

### 6.2.2.1 Fully Processed Semen

For semen fully processed prior to March 14, 2000, the following tests must have been performed:

- a. Minimum serological testing performed at least every 180 days while the donor remained an active participant in the program must have included tests for:
  - i. Hepatitis B surface antigen (HBsAg), unless the test for antibody to Hepatitis B core antigen (IgG anti-HBcAg) was done after a minimum quarantine period of 180 days; and
  - ii. *Treponema pallidum* (syphilis) using a non-treponemal test or a treponemal-specific test (FTA-ABS or MHA-TP), unless both the non-treponemal test and the treponemal-specific tests were done after a minimum quarantine period of 180 days; and
- b. Minimum serological testing performed after the semen was quarantined for a minimum of 180 days but before distribution must have included tests for:
  - i. antibody to HIV-1 and 2;
  - ii. antibody to HCV;
  - iii. hepatitis B surface antigen (HBsAg) or antibody to Hepatitis B core antigen (IgG anti-HBcAg);
  - iv. antibody to HTLV I and II; and
  - v. *Treponema pallidum* (syphilis) using:
    1. non-treponemal test; or
    2. treponemal-specific test (FTA-ABS or MHA-TP).

### 6.2.2.2 Partially Processed Semen

If, prior to March 14, 2000, semen has been processed but the repeat testing after a minimum quarantine period of 180 days has not been done, the repeat testing must be done in accordance with the requirements set out under Clause 4.2.2.

## 6.3 Microbiology

- a. For semen processed prior to March 14, 2000, the following minimum microbiological tests must have been performed at the “Work-up” stage and at least every 180 days while the donor remained an active participant in the program:
  - i. *Chlamydia trachomatis* using a nucleic acid amplification test on urine or urethral specimens; and
  - ii. *Neisseria gonorrhoeae* using
    1. urethral or semen cultures; or
    2. a nucleic acid amplification test on urine or urethral specimens.

- b. For semen processed prior to March 14, 2000 in respect of which the testing for *Chlamydia trachomatis* specified in clause 6.3(a)(i) has not been done, a nucleic acid amplification test for *Chlamydia trachomatis* must be performed:
  - i. on a semen specimen from the same donation as the semen that is to be distributed; or
  - ii. on semen specimens from two donations made within 180 days of each other by the donor of the semen that is to be distributed, one of which was made before the donation of the semen that is to be distributed and one of which was made after that donation.
- c. For semen processed prior to March 14, 2000 in respect of which the testing for *Neisseria gonorrhoeae* specified in clause 6.3(a)(ii) has not been done, a nucleic acid amplification test for *Neisseria gonorrhoeae* must be performed:
  - i. on a semen specimen from the same donation as the semen that is to be distributed; or
  - ii. on semen specimens from two donations made within 180 days of each other by the donor of the semen that is to be distributed, one of which was made before the donation of the semen that is to be distributed and one of which was made after that donation.

**Note:** Semen shall not be released for distribution if cultures rather than nucleic acid amplification tests were used for the detection of *Chlamydia trachomatis*.

- d. For semen processed prior to March 14, 2000, specimens collected between testing intervals in which *Chlamydia trachomatis* or *Neisseria gonorrhoeae* infection cannot be ruled out must be discarded.

#### 6.4 Other Measures

In respect of matters other than testing for infectious diseases, semen processed prior to March 14, 2000 must have been processed in accordance with either:

- a. The measures set out under the headings “Work-Up”, “Repeat Screening & Quarantine” and “Semen Microbiology” of the CFAS 1996 Guidelines; or
- b. The measures set out under the headings “Work-Up”, “Repeat Screening & Quarantine” and “Microbiology” of this Directive.

**Source:** HEALTH CANADA, “Health Canada Directive: Technical Requirements for Therapeutic Donor Insemination”, *Drugs and Health Products*, July 2000, [online], [http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/semen-sperme-acces/semen-sperme\\_directive-eng.php](http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/semen-sperme-acces/semen-sperme_directive-eng.php).

**TABLE 1** CYCLE OUTCOMES FOR THE MOST COMMON TYPES OF ART PROCEDURES

	IVF + ICSI	IVF + ICSI + OD	FET	FET + OD (or ED)
Cycles started	8,195	301	2,498	143
Clinical pregnancy <sup>1</sup>	2,631 (32.1)	140 (46.5)	569 (22.8)	36 (25.2)
Delivery <sup>1</sup>	2,097 (25.8)	102 (35.2)	437 (17.6)	27 (19.0)
Live birth <sup>1</sup>	2,076 (25.6)	102 (35.2)	433 (17.4)	26 (18.3)
Singleton live birth <sup>1</sup>	1,435 (17.7)	68 (23.4)	326 (13.1)	21 (14.8)
Singleton delivery <sup>2</sup>	1,451 (69.2)	68 (66.7)	330 (75.5)	22 (81.5)
Twin delivery <sup>2</sup>	616 (29.4)	34 (33.3)	100 (22.9)	5 (18.5)
Triplet delivery <sup>2</sup>	30 (1.4)	0	7 (1.6)	0

**Caption:**

ED: Embryo donation

FET: Frozen embryo transfer

ICSI: Intracytoplasmic sperm injection

IVF: *In vitro* fertilization

OD: Ovule donation

<sup>1</sup> % of cycles started<sup>2</sup> % of deliveries

Source: Joanne GUNBY *et al.*, "Assisted reproductive technologies in Canada: 2005 results from the Canadian Assisted Reproductive Technologies Register", *Fertility and Sterility*, 2009, vol. 91, n°5, pp. 1721-1730.

**TABLE 2 COMPARISON OF SINGLETON AND MULTIPLE BIRTHS**

	Singleton births	Twin births	Triplet births
	1,909 children	1,534 children	111 children
Still-births	21	18	1
Neonatal deaths	11	23	4
Total perinatal deaths	1.7%	2.7%	4.5%
< 37 weeks	17.3%	71.7%	100.0%
< 34 weeks	4.7%	22.7%	78.8%
Median gestationnel age <sup>1</sup>	39 weeks	36 weeks	31 weeks
Birth weight			
>2,500g	89.8%	43.0%	3.3%
2,000-2,500g	6.5%	36.2%	24.4%
1,000-1,999g	2.5%	17.1%	56.7%
<1,000g	1.2%	3.6%	15.6%
Rate of congenital defects	46 children (2.4%)	31 children (2.0%)	3 children (2.7%)

**Caption:**

<sup>1</sup> of live births

**Source:** Joanne GUNBY *et al.*, "Assisted reproductive technologies in Canada: 2005 results from the Canadian Assisted Reproductive Technologies Register", *Fertility and Sterility*, 2009, vol. 91, n°5, pp. 1721-1730.

**TABLE 3 CLINICAL PREGNANCY AND BIRTH OUTCOMES BY FEMALE AGE FOR THE THREE MOST COMMON ART PROCEDURES**

	IVF + ICSI	IVF + ICSI + OD	FET
Mean female age, years (range)	35 (19-53)	41 (26-51)	35 (23-52)
Cycles started by age			
<35	44.8%	15.0%	47.0%
35-39	37.2%	20.6%	37.3%
>40	17.9%	64.3%	15.8%
Clinical pregnancy by age			
<35	38.6%	46.5%	24.8%
35-39	30.8%	44.1%	22.9%
>40	18.7%	47.3%	16.7%
Live birth by age			
<35	32.4%	32.6%	19.8%
35-39	24.0%	31.6%	17.5%
>40	12.0%	36.0%	11.1%
Multiple birth by age			
<35	34.6%	35.7%	28.9%
35-39	26.8%	27.8%	17.4%
>40	21.6%	34.9%	25.6%

**Caption:**

**FET:** Frozen embryo transfer

**ICSI:** Intracytoplasmic sperm injection

**IVF:** *In vitro* fertilization

**OD:** Ovule donation

**Source:** Joanne GUNBY *et al.*, "Assisted reproductive technologies in Canada: 2005 results from the Canadian Assisted Reproductive Technologies Register", *Fertility and Sterility*, 2009, vol. 91, n°5, pp. 1721-1730.

**TABLE 4 CLINICAL PREGNANCY RATE PER EMBRYO TRANSFER PROCEDURE AND MULTIPLE BIRTH RATE PER KNOWN BIRTH BY NUMBER OF EMBRYOS TRANSFERRED IN IVF/ICSI CYCLES**

No. of embryos transferred	No. of cycles <sup>1</sup>	No. of pregnancies <sup>2</sup>	No. of births <sup>3</sup>	No. of total multiple births <sup>4</sup>	No. of triplet births <sup>4</sup>
1	10.7	20.1	5.6	3.6	0.0
2	57.3	41.8	66.3	33.1	0.7
3	23.1	36.0	21.0	29.8	2.9
4	5.8	35.6	5.1	35.6	4.0
5 or more	3.1	24.9	2.1	29.3	2.4

**Caption:**

<sup>1</sup> % of all embryo transfer cycles

<sup>2</sup> % per embryo transfer

<sup>3</sup> % of all births

<sup>4</sup> % per birth

**Source:** Joanne GUNBY *et al.*, “Assisted reproductive technologies in Canada: 2005 results from the Canadian Assisted Reproductive Technologies Register”, *Fertility and Sterility*, 2009, vol. 91, n°5, pp. 1721-1730.

**TABLE 5 EMBRYO TRANSFER RATE DURING IVF**

Number of embryos transferred	Canada (2005) <sup>1</sup>	United States (2000) <sup>2</sup>	France (2001) <sup>2</sup>	Belgium (2001) <sup>3</sup>
1	10.7	5.7	16.0	~ 15.0
2	57.3	25.8	31.8	~ 55.0
3	23.1	34.9	42.0	~ 25.0
4	5.8	21.6	10.2	~ 5.0
5 or more	3.1	12.0	0.0	0.0

**Sources:**

<sup>1</sup> Joanne GUNBY *et al.*, “Assisted reproductive technologies in Canada: 2005 results from the Canadian Assisted Reproductive Technologies Register”, *Fertility and Sterility*, 2009, vol. 91, n°5, pp. 1721-1730.

<sup>2</sup> J.-M. ANTOINE *et al.*, “Traitements de la stérilité et grossesses multiples en France: analyse et recommandations”, *Gynécologie Obstétrique & Fertilité*, 2004, vol. 32, n°7-8, p. 674.

<sup>3</sup> P. DE SUTTER *et al.*, “Une décennie d’enregistrement des données de la procréation médicalement assistée en Belgique”, *Revue Médicale de Bruxelles*, 2004, vol. 25, n°3, p. 162.



## COMPARATIVE TABLE OF AUTHORIZED ASSISTED PROCREATION PRACTICES, BY COUNTRY

Country	Persons able to obtain AP	AP <i>post mortem</i>	Gamete and embryo donation	Anonymity of gamete donation	Compensation for gamete donation	Surrogacy	PGD
AUSTRALIA		Australia, written consent in advance		Lifted in two States		Authorized	
AUSTRIA		Authorized	Only sperm donation is allowed	Lifted			Prohibited
AZERBAIDJAN			Embryo donation is prohibited				
BELGIUM	No legal limitation	Authorized	Authorized	Anonymity respected, Non-anonymous donations are the norm		Contract nullified according to provisions of civil law	PGD, PGD-HLA and genetic screening authorized, the gravity of the illness is not a criterion; sex selection is prohibited
BRAZIL						Authorized	
BULGARIA		Prohibited					
CANADA	Singles and homosexuals		Authorized	Maintained		Prohibition of inciting a woman under 21 years of age to become a surrogate mother	
CROATIA			Only sperm donation is allowed				
DENMARK	Single women and women in homosexual couple	Prohibited	Embryo donation prohibited	Maintained	Market for sperm	Monitored	
ECUADOR						Authorized	
ESTONIA						Authorized	
FINLAND	Single and homosexual women					Allowed	

Country	Persons able to obtain AP	AP <i>post mortem</i>	Gamete and embryo donation	Anonymity of gamete donation	Compensation for gamete donation	Surrogacy	PGD
FRANCE	Couples of child-bearing age + medical diagnosis	Prohibited	Authorized	Maintained		Prohibited	
GEORGIA						Open to married couples where the woman has no uterus	
GERMANY	Married couples and homosexual couples	Prohibited	Only sperm donation is allowed	Right to know ones origins is recognized		Prohibited	Prohibited
GREECE	Single women (homosexual women living as couples are accepted in practice)	Authorized		Maintained		Monitored, the surrogate mother may be compensated	
HONG KONG		Prohibited				Authorized	
HUNGARY						Authorized if parties are members of the same family	
ICELAND			Embryo donation prohibited				
INDIA		Authorized				Authorized	
IRAN						Authorized	
ISRAEL	No limitations	Authorized, time limit	Embryo donation prohibited			Open to married couples	Authorized and encouraged for couples at risk of transmitting incurable diseases; sex selection is allowed for parents who already have 4 children of the same sex

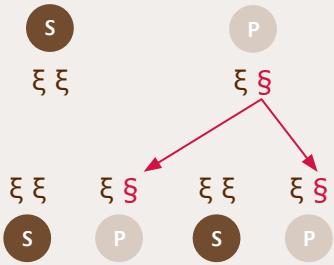
Country	Persons able to obtain AP	AP <i>post mortem</i>	Gamete and embryo donation	Anonymity of gamete donation	Compensation for gamete donation	Surrogacy	PGD
ITALY	Stable couples	Prohibited	Prohibited	Lifted		Prohibited	Restrictive policy
JAPAN		Prohibited				Prohibited	Criteria of gravity and incurability must be met
KOREA		Prohibited					
LITHUANIA			Prohibited				
NETHERLANDS	Single and homosexual women	Authorized		Lifted		Allowed, onerous contracts prohibited	
NEW ZEALAND		Authorized				Authorized	
NORWAY	Stable couples	Prohibited	Only sperm donation is allowed	Lifted		Prohibited	PGD, PGD-HLA based on criteria of gravity and incurability
PHILIPPINES						Prohibited	
POLAND				Maintained			
PORTUGAL	Stable couples		Embryo donation prohibited				
RUSSIA	Single people					Authorized	
SALVADOR						Authorized	
SERBIA-MONTENEGRO	Stable couples						
SINGAPORE		Prohibited				Prohibited	
SLOVENIA	Stable couples	Prohibited	Embryo donation prohibited				
SOUTH AFRICA		Authorized, written consent in advance				Authorized	
SPAIN	Single women	Authorized, limit of 6 months after death	Authorized	Maintained (non-identifying information may be divulged)	€ 900 per ovarian puncture	Prohibited	

Country	Persons able to obtain AP	AP <i>post mortem</i>	Gamete and embryo donation	Anonymity of gamete donation	Compensation for gamete donation	Surrogacy	PGD
SWEDEN	Female homosexual couples; medical, psychological and social decision	Prohibited	Embryo donation prohibited	Lifted		Prohibited	PGD-HLA authorized since 2007
SWITZERLAND	Stable couples	Prohibited	Only sperm donation is allowed	Lifted		Prohibited	Restrictive policy, possible opening for PGD-HLA
TAIWAN		Prohibited	Prohibited				
TURKEY							
UKRAINE						Authorized	
UNITED KINGDOM	No legal limitation	Authorized, written consent in advance, time limit in England	Authorized	Lifted for children born after 1 April 2005	Oocyte sharing means treatment at a lower cost	Authorized (free) and monitored	PGD and PGD-HLA authorized, the gravity of the illness is not a criterion, genetic screening is authorized on a case-by-case basis; sex selection is prohibited
UNITED STATES	Singles and homosexuals			Dual registry, no State has legislated in this area	Market for ovids and sperm with catalogue	Prohibited in certain States (Arizona, Washington, New Mexico, Utah, Michigan, New York), authorized in others (Arkansas, Florida, Nevada, Tennessee, Vermont, Ohio, Virginia, California)	Sex selection allowed
VIETNAM						Prohibited	

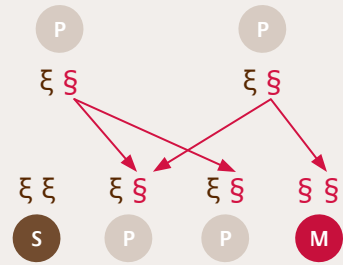
Sources: AGENCE DE LA BIOMÉDECINE, *Étude comparative de l'encadrement juridique international*, October 2008, [online], <http://www.agence-biomedecine.fr/fr/doc/bilanLB-partie2.pdf> and Marie-Pier BARBEAU, *L'apport d'un tiers au projet parental et le diagnostic préimplantatoire – Étude de droit comparé*, prepared for the Commission de l'éthique de la science et de la technologie, Québec, October 2008.



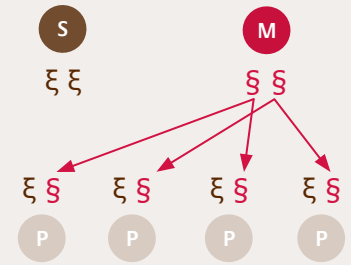
## DIAGRAM OF GENE TRANSMISSION PROBABILITIES



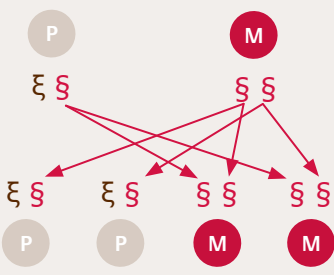
2 embryos out of 4 are healthy  
2 embryos out of 4 are carriers



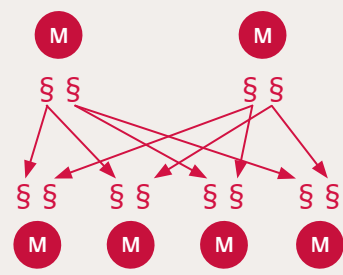
1 embryo out of 4 is healthy  
2 embryos out of 4 are carriers  
1 embryo out of 4 has the disease



4 embryos out of 4 are carriers



2 embryos out of 4 are carriers  
2 embryos out of 4 have the disease



4 embryos out of 4 have the disease

- § : Abnormal gene
- ξ : Normal gene
- S Healthy person or embryo
- P Carrier person or embryo
- M Person or embryo who will develop the disease

**ORAL CONTRACEPTIVES:** The oral contraceptive pill is used to prevent the formation of ovarian cysts in treatment (cysts are not dangerous but interfere with treatment), and to schedule the timing of the treatment so that appointments can be planned in advance. Oral contraceptives are prescribed for a short duration and are not usually associated with side effects.

**GONADOTROPINS (FSH AND LH):** Gonadotropins are hormones that signal the ovaries to produce eggs. These are prescribed to stimulate the ovaries to produce a number of mature eggs prior to egg retrieval. Gonadotropins are taken by subcutaneous injection on a daily basis for about two weeks. Most women who take gonadotropins do not have serious side effects but those who do report temporary side effects that include inflammation at the injection site, mood swings, breast tenderness, abdominal bloating/ discomfort, and headache.

**GnRH AGONIST / GnRH ANTAGONIST:** GnRH Agonist or Antagonist is prescribed to prevent ovulation during treatment. Both Agonist and Antagonist act on the brain to suppress the secretion of hormone (the “LH surge”) that normally provokes ovulation. GnRH Agonist and Antagonist are taken by subcutaneous (under the skin) injection on a daily basis. Side effects with GnRH Agonists are rare but some women may experience temporary menopausal-like side effects including hot flashes, headaches and mood changes. The use of Antagonist is not usually associated with side effects.

**hCG:** Human Chorionic Gonadotropin (hCG) is given to bring about the final maturation of eggs in preparation for fertilization. hCG is given by subcutaneous injection 35 hours before the scheduled egg retrieval. Side effects after hCG injection are extremely rare and include inflammation of the injection site and “ovulation- like” cramping. Additional hormone therapy is given after the egg retrieval, in order to help implantation of the embryo and to support the (hoped for) pregnancy. These include:

**ESTROGEN:** Estrogen helps develop and support the endometrium (lining of the uterus). Estrogen is taken as an oral medication on a daily basis through the first trimester of pregnancy. Side effects are rare but may include breast tenderness, mood changes, water retention, nausea, and fatigue.

**PROGESTERONE:** Progesterone plays an important role in supporting the endometrium in pregnancy. Progesterone is taken on a daily basis by intramuscular injection or by vaginal suppository through the first trimester of pregnancy. Side effects are rare but include reactions at the site of injection, swelling, mood changes, PMS-like symptoms, and rarely allergic reactions.

**MEDROL:** Medrol is a steroid that may help implantation. Medrol is taken by mouth and is begun prior to embryo transfer. Medrol is taken for a short duration and in this situation is rarely associated with side effects.

**DOXYCYCLINE:** Doxycycline is an antibiotic that is begun prior to embryo transfer, to help create a favourable environment for implantation. Doxycycline is taken orally.

**Source:** MCGILL REPRODUCTIVE CENTRE, *In vitro fertilization – Medication*, [online], <http://www.mcgillivf.com/e/McGillIVF.asp?page=184.186.210#Medication>.



## THE CONSULTATION ACTIVITIES OF THE COMMISSION AND CONTRACTED RESEARCH WORKS

### The following organizations and individuals made submissions:

M<sup>e</sup> Caroline Amireault, *Association des couples infertiles du Québec*  
Ms. Véronique Bergeron and Mr. Patrick Lavoie, *in their role as citizens*  
Ms. Nathalie Boëls, *Spina Bifida and Hydrocephalus Association of Québec*  
Ms. Mariangela Di Domenico, *Conseil du statut de la femme*  
Mr. Steve Foster, *Conseil québécois des gais et lesbiennes*  
Ms. Beverly Hanck, *Infertility Awareness Association of Canada*  
Dr. Yves Lamontagne, *Collège des médecins du Québec*  
Dr. Corinne Leclercq, *Association of Obstetricians and Gynecologists of Québec (AOGQ)*  
Ms. Nathalie Parent, *Fédération du Québec pour le planning des naissances*

### Online consultation on assisted procreation, from 3 September to 3 October 2008

**Number of participants:** 1,066  
**Women:** 82.36%; **Men:** 17.64%  
**30 to 44 years of age:** 50.09% ; **18 to 29 years of age:** 32.83%  
**Regions:** Montréal (27%), Québec (21%), Montérégie (14%), Laurentides (4-5%),  
Chaudières-Appalaches (4-5%), Estrie (4-5%), Laval (4-5%), Lanaudière (4-5%),  
Mauricie (2-3%), Outaouais (2-3%), Saguenay (2-3%), Abitibi-Témiscamingue (2-3%)  
et Centre du Québec (2-3%)  
**University degree (either completed or currently underway):** 63%  
**French (language spoken in the home):** 96%  
**Have a children by natural birth:** 45% ; **Adopted child:** 5% ; **Have tried AP:** 21%  
**Women having been solicited to bear a child for a couple:** 12 women  
**Men having donated sperm:** 7 men  
**Women having donated ovules:** 4 women

**The following people spoke during audiences of the working committee:**

**25 September in Montréal:**

Ms. Chantal Bouffard, *Anthropologist and professor at Université de Sherbrooke*  
Ms. Valérie Désilets, *Medical geneticist at Hôpital Ste-Justine*  
Ms. Beverly Hanck, *Infertility Awareness Association of Canada*  
Dr. Michèle Marchand, *Collège des médecins du Québec*

**26 September in Montréal:**

Ms. Nathalie Bolduc and Ms. Andrea Secord,  
*Genetic counsellors at the Montreal Children's Hospital*  
Dr. Robert Hemmings, *The Society of Obstetricians and Gynecologists of Canada*  
Dr. Karine Igartua, *Psychiatrist at the McGill Sexual Identity Centre*  
Ms. Louise Vandelac, *Sociologist and professor at the Université du Québec à Montréal*

**3 October in Québec:**

Ms. Carole Tardif and Ms. Sandra Villeneuve, *Association pour l'intégration sociale*  
Mr. Bernard Keating, *Professor in the Faculty of Theology at Université Laval*  
Mr. Thomas De Koninck, *Professor in the Faculty of Philosophy at Université Laval*  
M<sup>e</sup> Anne-Marie Savard, *Lawyer specializing in the rights of the person*

**The Commission granted short-term contracts to the following people:**

Ms. Marie-Pier Barbeau  
Ms. Valérie Bouchard  
Ms. Cynthia Pratte  
Ms. Renée Dolbec (for the French linguistic revision of an additional document)

**The Commission thanks all of these people for their contribution to developing and enhancing the content of its position statement on assisted procreation.**



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<sup>442</sup> When the present position statement was adopted.



