SUMMARY ADVISORY

ON ASSISTED REPRODUCTION

IN QUÉBEC

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Production

Health and Welfare Commissioner
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<td>ART</td>
<td>Assisted Reproductive Technologies</td>
</tr>
<tr>
<td>BORN</td>
<td>Better Outcomes Registry and Network</td>
</tr>
<tr>
<td>CARTR</td>
<td>Canadian Assisted Reproductive Technologies Register</td>
</tr>
<tr>
<td>CFAS</td>
<td>Canadian Fertility and Andrology Society</td>
</tr>
<tr>
<td>CHUQ</td>
<td>Centre hospitalier universitaire de Québec</td>
</tr>
<tr>
<td>CHUM</td>
<td>Centre hospitalier de l'Université de Montréal</td>
</tr>
<tr>
<td>CHUS</td>
<td>Centre hospitalier universitaire de Sherbrooke</td>
</tr>
<tr>
<td>CSSS</td>
<td>Centre de santé et de services sociaux</td>
</tr>
<tr>
<td>IVF</td>
<td>In vitro fertilization</td>
</tr>
<tr>
<td>INESSS</td>
<td>Institut national d’excellence en santé et en services sociaux</td>
</tr>
<tr>
<td>INSPQ</td>
<td>Institut national de santé publique du Québec</td>
</tr>
<tr>
<td>MSSS</td>
<td>Ministère de la Santé et des Services sociaux</td>
</tr>
<tr>
<td>MUHC</td>
<td>McGill University Health Centre</td>
</tr>
<tr>
<td>RAMQ</td>
<td>Régie de l’assurance maladie du Québec</td>
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A Word from the Commissioner

When I was tasked with issuing an advisory report on the relevance of providing certain assisted reproduction services and on the services that should be insured under the program, I knew that this would be a colossal and delicate exercise. I accepted the mandate with enthusiasm, however, knowing that my team was up to the challenge.

This topic raises fundamental issues involving numerous ethical and social concerns that need to be duly considered. We were very thorough, in an attempt to draw the most accurate picture possible of this complex mosaic. We also took our time, to ensure nothing was overlooked, and varied our approaches to obtain a range of viewpoints on the positions expressed.

We are now ready to present the process and the resulting five orientations and twelve recommendations. We have taken a balanced, realistic approach that takes into account current changes in social values with regard to assisted reproduction. The decisions required to improve the program will not be easy to make. I hope that this advisory report will be a helpful guide.

My thanks to the Consultation Forum members, who deliberated with passion and conviction on this delicate subject, concerned about the overall fairness and stability of our health and social services system. I would like to highlight the major contribution of some 500 Quebecers who shared their experiences through their testimonies. Without them this advisory report would not reflect the real-life situations behind the data and technical and financial aspects. I thank all the individuals and organizations who took the time to submit a brief and all those who we interviewed at the various clinics. They shared their knowledge and taught us a great deal about current practices.

Robert Salois
Introduction

In February 2013 the Health and Welfare Commissioner was asked by the minister of health and social services to issue an advisory report on the relevance of offering certain assisted reproduction services in Québec (see Appendix I). Under Section 9 of the Act respecting clinical and research activities relating to assisted procreation, the minister may ask the Commissioner for an advisory report when activities related to assisted reproduction raise ethical or social questions on fundamental issues concerning Québec society as a whole. In entrusting this mandate to the Commissioner, the minister indicated that the Ministère de la Santé et des Services sociaux (MSSS) had been asked for its position on various situations that raised such issues.

To carry out this mandate, the Commissioner collected data from a variety of sources—including broad public consultations—to obtain a range of viewpoints. This approach included a call for briefs, a call for testimony, meetings with the Consultation Forum, a literature review, quantitative surveys, individual interviews, site visits, and meetings with various professionals active in the field of assisted reproduction. An analysis of medico-administrative data was also performed.

Québec’s assisted reproduction program was launched in June 2010 in a complex social and political context where a number of stakeholders with varying interests clashed publically in the media.

While infertile couple associations, certain advocacy groups, and fertility specialists applauded the announcement of publicly funded assisted reproduction services and a better control of multiple pregnancies, administrators, doctors, and citizens, alike criticised the speed with which the program had been set up and the lack of adequate planning and oversight. They also reacted negatively to forecasts of exorbitant costs and the possibility of other health priorities being neglected due to resources allocated to the program.

A number of political considerations may have influenced the speed with which the Québec government established the program’s framework and funding. Lay associations and fertility specialists had been lobbying for recognition of infertility as an illness for a number of years. There was also a desire to assert Québec’s jurisdiction over assisted reproduction after the federal law on assisted reproduction was passed in 2004.

According to certain groups, the assisted reproduction program and its funding reflect a societal approach that favours technology over other ways of supporting families, such as adoption or infertility prevention. Religious groups of various denominations also expressed concerns about the instrumentalization of the
human embryo. Feminists have traditionally taken a range of positions on the
development of assisted reproductive technologies (ART): some see these
techniques as a way of promoting reproductive autonomy for women, while
others see it as a potential means of subservience.

Changing values in Québec society, particularly concerning the emancipation of
women, have tended to delay childbirth and lead to an increased demand for
assisted reproduction. The amendment to the Civil Code of Québec in 2002
(Section 578.1) recognizing the parental relationship of female same-sex couples
with children born through assisted reproduction led same sex couples to aspire
to the same access to assisted reproduction services as heterosexual couples.

This summary advisory comprises three chapters. The first provides an overview
of assisted reproduction in Québec, the rest of Canada, and a number of other
countries. The second chapter presents the main data collected on assisted
reproduction in Québec since the program was launched. The third details the
Commissioner's recommendations to realign Québec's assisted reproduction
program.

This summary covers the main points included in the Commissioner's detailed
advisory report on assisted reproduction. The detailed report, released at the
same time as the summary, presents a comprehensive overview of all the
information collected in support of the recommendations. Quotes from the briefs,
testimonies, and deliberations of the Commissioner's Consultation Forum as well
as certain findings from the Léger survey conducted on the Commissioner's
behalf are highlighted in support of the argumentation. The summary advisory
includes a number of relevant quotes from the Consultation Forum, considering
the special nature of the Forum's role set out in the Commissioner's act of
incorporation.
Chapter 1: Assisted Reproduction in Québec and Around the World

Financial support for assisted reproduction in Québec started with an initial Québec tax credit for infertility treatments in the 2000–2001 budget. The tax credit was increased twice before the assisted reproduction program was launched in August 2010.

In 2004, the federal government passed legislation on the use of reproductive technologies. The *Assisted Human Reproduction Act*\(^1\) covered assisted reproductive technologies and procedures, as well as related research. It criminalized certain practices such as human cloning and embryo research, and also prohibited payment for surrogacy and the purchase of gametes (eggs and sperm), but authorized donation of gametes. The Québec government contested the constitutionality of a number of clauses in the Canadian act, and the Supreme Court of Canada ruled in December 2010 that the responsibility for clinical activities fell under provincial jurisdiction.\(^2\) However, the federal government reserves the right to legislate on moral issues such as prohibiting the sale of embryos or payment of gamete donors.

**Québec Assisted Reproduction Program**

According to statements made by the minister of health and social services in August 2010 when the assisted reproduction program was launched, the three main objectives of the program were to reduce multiple pregnancies, enable infertile couples to have children, and boost Québec's birth rate. The stated target was to reduce the rate of multiple pregnancies following in vitro fertilization (IVF) from 25%–30% to 5%–10% and increase the number of live-born infants by 1,000 to 1,500 a year. The minister considered that the estimated $100 million in savings generated by reducing the number of multiple births and the number of hospital stays in neonatal intensive care would offset the cost of the proposed program.

The pursuit of this objective in the past, whether official or not, has led to all sorts of abuses that must not be repeated.

Consultation Forum deliberations, November 2013

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Regulatory framework for the Assisted Reproduction Program

The legislative framework for the program is based on the Act respecting clinical and research activities relating to assisted procreation\(^3\), the Regulation respecting clinical activities related to assisted procreation\(^4\), and the Regulation amending the Regulation respecting the application of the Health Insurance Act\(^5\).

The Act respecting clinical and research activities relating to assisted procreation includes provisions on the issuing by the minister of licenses required for the delivery of assisted reproductive care. The Regulation respecting clinical activities related to assisted procreation sets out the conditions and standards governing permits and clinical assisted reproduction services. The Regulation amending the Regulation respecting the application of the Health Insurance Act specifies the services covered by the Régie de l’assurance maladie du Québec (RAMQ).

Assisted Reproductive Technologies

Section 2 of the Act respecting clinical and research activities relating to assisted procreation indicates that “assisted procreation activities means any support given to procreation by medical or pharmaceutical techniques or laboratory manipulation . . .”. The act particularly targets “the use of pharmaceutical procedures to stimulate the ovaries; the removal, treatment, in vitro manipulation, and conservation of human gametes; artificial insemination with a spouse’s or a donor’s sperm; preimplantation genetic diagnosis; embryo conservation; embryo transfer in women.”

Assisted reproduction uses a number of technologies, whose complexity and consequences vary. These services include relatively simple medical acts, such as artificial insemination, as well as more complicated high-tech procedures such as IVF.

Artificial insemination involves the introduction of a sufficient amount of sperm in a woman’s reproductive system, usually the uterus, to fertilize the woman’s eggs in vivo. IVF is indicated for specific causes of infertility or situations where other approaches (ovarian stimulation, artificial insemination, or various surgical or pharmaceutical treatments for infertility) have failed. Complete obstruction of the Fallopian tubes, severe endometriosis, and severe male infertility are some of the conditions for which IVF is indicated.

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\(^3\) Québec (2009). Act respecting clinical and research activities relating to assisted procreation, CQLR, Chapter A-5.01, updated to March 1, 2014, Québec City, Éditeur officiel du Québec.

\(^4\) Québec (2010). Regulation respecting clinical activities related to assisted procreation, CQLR, chapter A-5.01, r. 01, Québec City, Éditeur officiel du Québec.

\(^5\) Québec (2010). Regulation amending the Regulation respecting the application of the Health Insurance Act: CQLR, chapter A-29, r. 5, Québec City, Éditeur officiel du Québec.
Organization of Services

The Act respecting clinical and research activities relating to assisted procreation stipulates that assisted reproductive care must take place only in “centers for assisted procreation” that hold a license issued by the minister. These centers may be located in an institution or private health facility within the meaning of the Act respecting health services and social services. The designation as a “center for assisted procreation” means that the center is authorized to provide a full range of fertility treatments, including IVF. To do so, it must have an embryology and andrology laboratory. Such centers are considered as specialized centers and are viewed as providing tertiary services. However, certain less complex clinical activities can be practiced outside these specialized centers.

There are three public, hospital-based centers for assisted reproduction in Québec, located at the McGill University Health Centre (CU SM), the Centre hospitalier de l’Université de Montréal (CHUM), and the Centre hospitalier universitaire Sainte-Justine. There are currently six centers for assisted reproduction in private facilities: the Clinique Procréa in Montréal and Québec City, the Clinique Ovo in Montréal, the Montreal Fertility Center, the OriginElle Fertility Clinic\(^6\), and the Fertylis center in Laval. These are private centers under agreement (hereinafter private centers).

There are also four regional public centers designated to provide some ART services closer to home to Quebecers living outside major urban centers: Centre de santé et de services sociaux (CSSS) de Chicoutimi, Centre hospitalier régional de Trois-Rivières, Centre hospitalier universitaire de Sherbrooke (CHUS), and Centre hospitalier universitaire de Québec (CHUQ). These designated regional centers provide all ART treatments except for the IVF steps requiring a local embryology laboratory. Patients thus have access to ovarian stimulation and artificial insemination services in their regional center. They can also start their IVF cycles and receive the necessary follow-up after embryo transfer.

Funding for Assisted Reproduction

The Regulation amending the Regulation respecting the application of the Health Insurance Act specifies what services are covered by the RAMQ. They include ovarian stimulation (ovulation induction), artificial insemination, surgical retrieval of sperm, retrieval of eggs or ovarian tissue (including for egg donation), IVF (including intracytoplasmic sperm injection and assisted embryo hatching, if needed), embryo transfer, preimplantation genetic diagnosis, cryopreservation of embryos, and freezing and storage of sperm. The regulation specifies that three

\(^6\)In 2013 the Montreal Reproductive Centre changed its name to the OriginElle Fertility Clinic and Women’s Health Centre.
stimulated IVF cycles are covered by the program and that good quality embryos produced by an IVF cycle must be transferred one by one before another full IVF cycle is begun to retrieve more eggs.

Drugs used for assisted reproduction are covered according to the usual conditions. RAMQ covers drugs for individuals registered under the public drug insurance plan. Those with a group plan are covered by their private insurers, and coverage under private plans must at least equal that of the public plan. However intended parents may have to pay substantial amounts for additional drug-related costs.

**Conditions Governing Access to Assisted Reproductive Care**

Unlike most other provinces and countries that provide publically funded ART procedures or treatments, very few criteria limiting access to the program have been defined in Québec. No precise reproductive age is specified in the act or its associated regulations, which leaves room for interpretation and medical judgment. In the absence of eligibility criteria, services are available both to couples diagnosed as infertile and to single women and same-sex couples.

**Situation in Other Canadian Provinces**

Since the 2010 Supreme Court of Canada ruling on the Assisted Human Reproduction Act, it is recognized that each province is responsible for its own clinical activities relating to assisted reproduction. At the time of the ruling, only Québec had drafted a law on assisted reproduction. To our knowledge, no other province or territory in Canada has enacted legislation governing this field of practice. Therefore no province has established eligibility criteria for assisted reproduction through legislation, whether it be criteria based on age, marital status, or sexual orientation, for example.

Ontario, Manitoba, Saskatchewan, and British Columbia have adopted government policies on funding assisted reproduction. They are among those that reimburse all or part of the basic fertility assessment costs. Artificial insemination is covered by public insurance in Ontario, Saskatchewan, and British Columbia. Manitoba offers a 40% tax credit of up to $8,000 a year that applies to all available services and causes of infertility.

Ontario is the only province outside Québec that reimburses IVF treatments, but only for patients whose infertility is due to complete, nonsurgical blockage of both Fallopian tubes. Ontario had a more comprehensive program providing access to assisted reproduction services prior to 1994, but in the wake of efforts to streamline “nonessential” health services and the tabling of the report of the Royal Commission on New Reproductive Technologies, IVF services for other conditions were withdrawn from the fee agreements with physicians and from the Ontario health insurance plan.
**Situation in Other Countries**

Many countries have regulated and financially support various ART procedures. The next two tables summarize the information presented in *Encadrement juridique international dans les différents domaines de la bioéthique. Actualisation 2012*, a report published by France’s Agence de la Biomédecine.

**Table 1. Types of regulatory frameworks for assisted reproduction around the world**

<table>
<thead>
<tr>
<th>Legislation on Assisted Reproduction</th>
<th>Members of the European Union</th>
<th>Specific legislation</th>
<th>General legal framework</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries outside the European Union with legal frameworks for assisted reproduction</td>
<td></td>
<td>Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Netherlands, Portugal, Slovenia, Spain, Sweden, United Kingdom</td>
<td>Cyprus, Ireland, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All members of the European Union (except Cyprus, Czech Republic, Estonia, Finland, Hungary, Lithuania, and Poland)</td>
<td>Argentina, Brazil, China, India, Ireland, Japan, the Philippines, Singapore, Thailand, United States</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control Mechanisms</th>
<th>Inspections</th>
<th>Administrative or penal sanctions</th>
<th>No legal or professional framework</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Greece, Netherlands, New Zealand, Russia</td>
<td>France, Germany, Greece, Italy, Netherlands, Norway, Sweden, United Kingdom</td>
<td>Colombia, Ecuador, Jordan, Malaysia, Peru, Uruguay, Venezuela</td>
</tr>
</tbody>
</table>
Table 2. Overview of funding methods and eligibility conditions for assisted reproduction services around the world

<table>
<thead>
<tr>
<th>Funding</th>
<th>Countries that reimburse certain assisted reproduction treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries that do not reimburse assisted reproduction treatments</td>
<td>Ireland, Switzerland, Ukraine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Eligibility Conditions</th>
<th>Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Israel, Italy, Macedonia, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Turkey, United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable couples diagnosed as being infertile</td>
<td>Belgium, Denmark, Finland, Greece, Israel, Netherlands, Norway, Russia, Spain, Sweden, United Kingdom, United States,</td>
</tr>
<tr>
<td>Access extended to single women and same-sex couples</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 2: Assisted Reproduction Program in Numbers?

To develop a quantitative picture of Québec's assisted reproduction program, the Commissioner relied on the MSSS MED-ÉCHO hospital admissions database as well as various RAMQ databases concerning fee-for-service medical services and pharmaceutical services related to assisted reproduction.

The short period of time since the launch of the assisted reproduction program should be kept in mind when interpreting the data, especially the temporal trends. Indeed, the data on births and babies conceived through assisted reproduction (mainly IVF) are available for only two full years. Data on the cost of hospital stays were not available for 2012–2013 at the time of the analysis. However, some data on ART procedures are available from August 2010 onwards, and some from before that date. It should be noted that the data available for analysis from the MED-ÉCHO and RAMQ databases were not linked, and the same is true for the data on mothers and babies. Moreover, it is not possible to link the data on men and women using assisted reproduction, because only the clinics have this information.

Even if the number of children conceived through assisted reproduction has increased significantly, the demographic impact of children born through IVF is relatively small, representing only 2% of births recorded in the MED-ÉCHO database in 2012–2013 (see Table 3).

Table 3. Annual number and proportion of newborns conceived through assisted reproduction

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Live-born Babies conceived Through Assisted Reproduction</th>
<th>Proportion of Live-born Babies conceived Through Assisted Reproduction (%)</th>
<th>Total Number of Live-born Babies*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009–2010</td>
<td>1,057</td>
<td>1.23</td>
<td>85,610</td>
</tr>
<tr>
<td>2010–2011</td>
<td>1,021</td>
<td>1.20</td>
<td>85,304</td>
</tr>
<tr>
<td>2011–2012</td>
<td>1,243</td>
<td>1.45</td>
<td>85,491</td>
</tr>
<tr>
<td>2012–2013</td>
<td>1,723</td>
<td>2.02</td>
<td>85,370</td>
</tr>
</tbody>
</table>

*Newborns born in or transferred to a hospital only.

See the detailed advisory report for more data on assisted procreation activities.
As regards the objective of reducing multiple pregnancies the data confirm that the program and its rules regarding the transfer of single embryos have reduced this risk. The percentage of multiple pregnancies among IVF pregnancies has dropped significantly. Out of the total number of live-born children conceived through assisted reproduction, the proportion of newborns from multiple pregnancies has substantially decreased from 38.5% in 2009–2010 to 17.2% in 2012–2013 (see Table 4). Although this approximately 55% decrease is remarkable, one out of six babies conceived through assisted reproduction are still the result of multiple pregnancies, compared to one out of forty spontaneously conceived babies.

Table 4. Number of live-born babies from multiple pregnancies among newborns conceived spontaneously or through assisted reproduction

<table>
<thead>
<tr>
<th>Year</th>
<th>Babies Conceived Through Assisted Reproduction</th>
<th>Babies Born Following Spontaneous Conception</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Babies from Multiple Pregnancies</td>
<td>%</td>
</tr>
<tr>
<td>2009–2010</td>
<td>407</td>
<td>38.5</td>
</tr>
<tr>
<td>2010–2011</td>
<td>393</td>
<td>38.5</td>
</tr>
<tr>
<td>2011–2012</td>
<td>287</td>
<td>23.1</td>
</tr>
<tr>
<td>2012–2013</td>
<td>297</td>
<td>17.2</td>
</tr>
</tbody>
</table>

The proportion of multiple births out of the total number of births resulting from spontaneous conception has remained stable. Of all the live-born babies from multiple pregnancies, 15.2% were conceived through assisted reproduction in 2009–2010 and 12.3% in 2012–2013. However, the risk of multiple births remains significantly higher with IVF than with spontaneous conception.
Québec’s results regarding the reduction of multiple births are excellent compared to those in the rest of Canada and other countries around the world.\(^8\)

While the proportion of multiple pregnancies has decreased, so too has the proportion of premature babies conceived through IVF as well as the proportion of those who have been hospitalized in neonatal intensive care units. In four years, the proportion of premature babies has dropped from nearly 30% to 19% and the proportion of babies sojourning in neonatal intensive care has decreased from nearly 19% to approximately 12% (see Table 5). However, in light of the risks associated with premature birth, these rates are still high. The reduction in premature births is mainly noticeable for women under age 40.

**Table 5. Number and proportion of premature babies and newborns hospitalized in neonatal intensive care units among newborns conceived through assisted reproduction and among all newborns**

<table>
<thead>
<tr>
<th>Year</th>
<th>Babies Conceived Through Assisted Reproduction</th>
<th>All Newborns</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Premature Babies (and %)</td>
<td>Number of Babies in Intensive Care (and %)</td>
</tr>
<tr>
<td>2009–2010</td>
<td>313 (29.61%)</td>
<td>199 (18.83%)</td>
</tr>
<tr>
<td>2010–2011</td>
<td>241 (23.60%)</td>
<td>157 (15.38%)</td>
</tr>
<tr>
<td>2011–2012</td>
<td>257 (20.68%)</td>
<td>169 (13.60%)</td>
</tr>
<tr>
<td>2012–2013</td>
<td>329 (19.09%)</td>
<td>204 (11.84%)</td>
</tr>
</tbody>
</table>

A number of variables indicate that women using assisted reproductive technologies and their babies receive more services. These variables include the

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\(^8\) For example in the United States, 46.4% of babies conceived through IVF were born following a multiple pregnancies in 2010. Canadian data are expressed as multiple pregnancies rather than multiple births. In 2012 the rate of multiple pregnancies in Canada among viable pregnancies was 22.9%, whereas the comparable rate was 6.8% in Québec according to the Canadian ART Registry (CARTR). It should be noted that the proportion of multiple pregnancies recorded at birth in Québec is higher: 9.45% in 2012–2013 according to the MED-ÉCHO database.
number of caesarean sections, antenatal hospital stays for mothers, and hospitals stays for newborns in neonatal care units, as well as the length of stay of newborns after birth. These findings, described in the detailed advisory report, are not surprising in themselves. A number of studies have demonstrated a higher risk of caesarean sections and higher costs during the prenatal and neonatal period following assisted reproduction.

The proportion of women hospitalized before delivery is systematically higher for women who have conceived through assisted reproduction (32.2%–37.4%) compared to other women (20.9%–23.7%). Furthermore, the gap is widening between the two groups, and the overall number of women hospitalized is increasing, as shown in Table 6.

**Table 6. Number and percentage of women hospitalized during the antenatal period in each group**

<table>
<thead>
<tr>
<th>Year</th>
<th>Pregnancies Resulting from Assisted Reproduction</th>
<th>Pregnancies Resulting from Spontaneous Conception</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Women Hospitalized</td>
<td>%</td>
</tr>
<tr>
<td>2009–2010</td>
<td>292</td>
<td>32.19</td>
</tr>
<tr>
<td>2010–2011</td>
<td>306</td>
<td>34.42</td>
</tr>
<tr>
<td>2011–2012</td>
<td>418</td>
<td>36.03</td>
</tr>
<tr>
<td>2012–2013</td>
<td>653</td>
<td>37.40</td>
</tr>
</tbody>
</table>

The overall cost of hospital stays in neonatal intensive care units following assisted reproduction are increasing rather than decreasing, as shown in Table 7. Therefore the program has not turned out to be self-financing as was predicted. The absolute number of babies conceived through assisted reproduction sojourning in neonatal intensive care has not decreased and although the average cost of hospital stays have increased for all, they have risen more quickly for babies conceived through assisted reproduction. The average length of stays in neonatal intensive care for these babies exceeds that of spontaneously conceived babies by about five days.
Table 7. Annual average cost of hospital stays in neonatal intensive care units for babies born following assisted reproduction and spontaneous conception, and the difference in average costs between the two groups

<table>
<thead>
<tr>
<th>Year</th>
<th>Babies Conceived Through Assisted Reproduction</th>
<th>Babies Born Following Spontaneous Conception</th>
<th>Difference in Average Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Average Cost ($)</td>
<td>Number</td>
</tr>
<tr>
<td>2009–2010</td>
<td>199</td>
<td>19,990</td>
<td>4,554</td>
</tr>
<tr>
<td>2010–2011</td>
<td>157</td>
<td>22,832</td>
<td>4,640</td>
</tr>
<tr>
<td>2011–2012</td>
<td>169</td>
<td>28,418</td>
<td>4,436</td>
</tr>
<tr>
<td>2012–2013</td>
<td>204</td>
<td>–</td>
<td>4,426</td>
</tr>
</tbody>
</table>

Analysis of medical services billed on a fee-for-service basis indicates a steady increase in the number of medical procedures billed. More than 12,000 women have received IVF-related services between program launch and March 31, 2013, while more women had access to artificial insemination or ovarian stimulation. The total cost of each type of procedure has been steadily increasing (see Table 8), except for fertility assessments and IVFs. Reimbursement rate changes introduced on January 1, 2012, which reduced the amount allotted for one IVF cycle from $7,100 to $4,750, explain the smaller amount earmarked for IVF in 2012–2013. It is interesting to note that in 2012 the three main procedures involved in an IVF cycle (ovarian stimulation for IVF, retrieval of eggs during a stimulated cycle, and transfer of fresh embryos) were still among the ten procedures on which RAMQ spent the most.
Table 8. Overall cost estimate of procedures billed to RAMQ for fertility assessments, initial visit in an assisted reproduction center, ovarian stimulation without IVF, artificial insemination, sperm straws, and IVFs

<table>
<thead>
<tr>
<th>Year</th>
<th>Fertility Assessment ($)</th>
<th>Initial visit ($)</th>
<th>Ovarian Stimulation Without IVF ($)</th>
<th>Artificial Insemination ($)</th>
<th>Sperm Straws ($)</th>
<th>IVF ($)</th>
<th>Overall Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009–2010</td>
<td>–</td>
<td>–</td>
<td>290,202</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>290,202</td>
</tr>
<tr>
<td>2010–2011</td>
<td>1,550,495</td>
<td>589,304</td>
<td>1,382,068</td>
<td>1,939,510</td>
<td>571,103</td>
<td>16,406,427</td>
<td>22,438,907</td>
</tr>
<tr>
<td>2011–2012</td>
<td>1,359,943</td>
<td>985,175</td>
<td>2,667,754</td>
<td>3,295,726</td>
<td>1,502,825</td>
<td>33,671,279</td>
<td>43,482,702</td>
</tr>
<tr>
<td>2012–2013</td>
<td>811,398</td>
<td>1,282,653</td>
<td>3,267,088</td>
<td>3,390,535</td>
<td>1,617,390</td>
<td>30,752,642</td>
<td>41,121,706</td>
</tr>
<tr>
<td>Total</td>
<td>3,721,836</td>
<td>2,857,132</td>
<td>7,316,910</td>
<td>8,915,973</td>
<td>3,691,318</td>
<td>80,830,348</td>
<td>107,333,517</td>
</tr>
</tbody>
</table>

Prescriptions and the cost of drugs covered under the public drug insurance plan for assisted reproduction have also increased from year to year. Drug costs are significantly higher for women using IVF than women using only artificial insemination or ovarian stimulation without IVF. The amounts listed in Table 9 concern about 21% of women who have used ART services and are registered with the public drug insurance plan. If this percentage is taken into account, the total amount spent on drugs—including public expenditures and those by private insurance plans and the individuals themselves—would come to approximately $36 million for 2012–2013 alone, compared to the $8.6 million earmarked in the public drug insurance plan.
Table 9 presents the cost of drugs and all services billed on a fee-for-service basis, including the amounts in Table 8, as well as expenses for surgical retrieval of sperm, supplements paid for deliveries and caesarean sections after IVF, and outpatient care for complications related to assisted reproduction. According to these data, the RAMQ and the public drug insurance plan have spent more than $131 million over four years. Although this estimate includes many procedures related to assisted reproduction, it is not exhaustive since it does not include additional appointments with other specialists or health professionals, for example. Government investments in new assisted reproduction centers are likewise not included.
Chapter 3: Findings and Recommendations

A certain number of arguments were presented to the Commissioner, questioning whether Québec's assisted reproduction program should be maintained. However, every argument has a counter-argument, depending on one’s perspective. The Commissioner found that Québec society is very much divided on this point. Social values regarding assisted reproduction and the priority it should be given are changing. The questions put to the Commissioner are thus fundamentally ethical issues, and a nuanced approach is required that is consistent with other societal choices Québec has made.

In light of the results obtained to date, the Commissioner believes that it is preferable to maintain the assisted reproduction program. However, he shares the opinion that the program was implemented without sufficient oversight, or adequate data to support the decision. The status quo is unacceptable.

Therefore the Commissioner recommends the following:

- The government should maintain Québec's assisted reproduction program but should make significant changes to clarify its objectives and redefine its eligibility criteria, while providing the means to assess whether the program’s objectives have been met.
- The program should be re-evaluated after the recommended measures have been implemented, and adjusted based on ensuing results in order to ensure its long-term viability and social acceptability.

Given the concerns expressed, the Commissioner has formulated recommendations targeting the following five goals:

- Ensure the sustainability and acceptability of the program
- Build program capacity for evaluation, reflection, and action
- Improve the quality of care and services
- Respond to psychosocial issues
- Deliberate on ethical issues and societal choices

3.1 Ensure the Sustainability and Acceptability of the Program

Recommendation 1: Establish limits on access to the program and prioritize the least invasive techniques

A program such as the assisted reproduction program should be in line with societal values, especially as assisted reproduction raises many ethical and social issues. Certain issues are associated with the lack of limits imposed on program access and with some of the current technical possibilities of assisted reproduction. Besides the abuses reported in the media, the Commissioner was
informed through his consultations of a number of problem situations, some of which were discussed by the members of the Consultation Forum (see Appendix XIV of the detailed advisory report).

It is important to clarify how Quebecers view assisted reproduction and how this vision can guide the direction the program should take. Assisted reproductive technologies were initially developed to address cases of medical infertility. As Québec society evolved, a combination of contextual factors led these technologies to take on a new, more social meaning. Some people now view assisted reproduction as a means to achieve de facto reproductive equality. The legal context in Québec tends to reinforce this vision. This de facto equality is often understood as an equal right to have children, which is not a recognized positive right.

So we have the medical perspective resting on the appropriateness of means used to address a medical problem on the one hand, and the social perspective seeking to provide equal access to reproductive outcomes on the other. These two visions, based on individuals’ fundamental values, may seem impossible to reconcile: neither can be rejected out of hand because both are legitimate within Québec society. The findings from the Commissioner’s consultations attest to the fact that society is truly divided with respect to these values.

Given the above, the Commissioner believes that it is important to achieve a balance between these two visions. Indeed, the medical and social perspectives are closely related to the program’s main objectives, namely to address the problem of medical infertility and to enable everyone to have children, by making the program accessible to all Quebecers. However, the Commissioner considers it important to set eligibility criteria applicable to all, with a view to the fair and equitable use of resources, and to prioritize the least invasive techniques according to what is medically indicated.

Rather than limiting access solely to cases of medical infertility, the Commissioner proposes that universal access to ART services be officially recognized, but that clear, acknowledged boundaries be established, at two levels. First, eligibility criteria that are applicable to all and based on specific factors such as the odds of success should be implemented to prevent ill-considered expenditures. Second, the choice of techniques used should be based on what is medically indicated rather than on the wishes of the individuals concerned. For example, the more invasive, risky, and costly IVF procedure should be reserved for situations where pregnancy cannot be achieved in any other way. Consultation Forum members reacted to this issue, as this excerpt from their deliberations shows:

Forum members were surprised, and even appalled in certain cases, to learn that there are no criteria for determining who is eligible for the program and under what conditions. . . . They noted that this lack of criteria may lead not
only to abuse, but even worse, to dramatic situations where children are conceived under circumstances bordering on science fiction, children who were never party to the decision and who may find themselves unwanted or even fought over like a simple consumer good by multiple adults.

Consultation Forum deliberations, September 2013

For the first category of criteria, the existing program imposes no limit on the number of children intended parents already have or the number of children conceived through assisted reproduction. After each live birth, the couple is again fully eligible for three IVF cycles. The Commissioner believes that the program should be more restrictive and should reimburse assisted reproduction services for up to three IVF cycles, for one child only, and on the condition that one of the intended parents has no children. In addition, anyone who has already received three IVF cycles should not be eligible for additional IVF procedures free of charge, even with another partner. The notion of imposing a limit on the number of children conceived through assisted reproduction was supported by half the respondents to a representative survey conducted by Léger for the Commissioner. This measure should generate savings by reducing the number of IVF cycles by 15% to 20%.

In the interests of the child, parental capacity should be an eligibility criterion when there is serious doubt about risks to the child (see Recommendation 9). The Commissioner also considers it appropriate to impose a maximum and minimum parental age limit. These limits should be established based on social consensus. In the current context of limited resources, the Commissioner considers that individuals who have chosen voluntary sterilization as a method of contraception should pay for the cost of ART services themselves. He also believes that public funds should not be used for retrieving and storing gametes to maintain fertility in the absence of a medical reason (such as cancer treatment). Lastly, the Commissioner deems it essential to systematically record data from both partners when ART services are sought and to ensure that they both hold valid RAMQ medical insurance cards in order to prevent certain forms of medical tourism.

The Commissioner feels that the potential success rate should also be an eligibility criterion. No procedure should be performed if the predicted success rate is below 5% to 10%, for example, to avoid futile, costly, and potentially risky procedures. The method of predicting the success rate for each woman or couple wishing to take advantage of ART services should be standardized and guidelines attaining province-wide consensus should be developed. A combination of factors must be taken into account to predict the success rate, including the age of women using their own eggs, the quality and quantity of gametes available from both partners, prior attempts at assisted reproduction and their results, smoking habits, and body mass index. Professional
assessment of each clinical situation should be based on guidelines developed in light of up-to-date evidence-based data. Until such consensual guidelines are developed, the Commissioner believes that clinics should adopt a moratorium on IVF for women over the age of 42 who wish to use their own eggs. This age limit was proposed by an expert committee in Ontario and is already used in a number of clinics in Québec. The risks for the health of the mother and child should also be taken into consideration. For example, severe maternal obesity increases the risk of preterm delivery, while smoking may cause fetal growth retardation and reduce male and female fertility. If there is a risk of transmitting serious monogenic diseases or a risk of chromosomal abnormalities, preimplantation diagnosis, and thus IVF, may be warranted, but criteria applicable to all must be established to guide decision-making.

As for the second category of boundaries, it is important to stress that the government has the right to set limits on reimbursement of certain services given limited resources. Other governments have done so in the past and some are very restrictive. Ontario, for example, reimburses the cost of IVF only in cases where both Fallopian tubes are completely blocked.

Even though we recommend maintaining universal access to the program, the choice of techniques used to conceive a healthy child should rest on the logic of appropriateness of means. This resource allocation approach is essential in a context where the health and social services system currently fails to meet many other health priorities. As a general rule, more sophisticated, risky, and costly techniques are avoided unless justified by the medical condition. Yet this logic is not always applied to assisted reproductive technologies.

The Commissioner believes that services should not be reimbursed in situations which are not in line with this logic. This applies particularly to IVF, but should also apply to other interventions such as surgical retrieval of sperm after surgical sterilization and to the referrals for assisted reproduction. Referrals are sometimes issued before recommended waiting periods have elapsed, before an infertility diagnosis is made or services are offered, and without providing the required explanations on methods to promote natural conception.

To determine which techniques are appropriate for the most common scenarios and in what order of priority, the Institut national d’excellence en santé et en services sociaux (INESSS) should develop evidence-based guidelines in conjunction with experts in the field. These guidelines should include the clinical pathways and the waiting periods to be upheld before resorting to ART in general, and IVF in particular.
Commissioner’s Recommendations

1.1 Impose limits on access to the program, applicable to all, based on the following factors:

- Eligibility of both partners for the Québec health insurance plan
- Prior voluntary sterilization
- Fertility preservation for social reasons
- Results of psychosocial assessment, if applicable
- Age of the mother (minimum and maximum)
- Number of existing children and number of children conceived through IVF

1.2 Establish consensual guidelines on how to take into account potential success rates (based in part on maternal age) and risk factors for the health of the mother and child (such as genetic factors) as eligibility criteria for the program.

1.3 Use the least invasive techniques possible based on what is medically indicated.
Recommendation 2: Promote more equitable access in Québec’s regions

Most specialized assisted reproduction centers are currently located in Montréal. This is due to the fact that these services were initially set up in the private sector. Deployment of these services was therefore not planned, and when the assisted reproduction program was launched, it relied mostly on existing services. When the government announced the program, it clearly stated its intention to set up public services and ensure the transition of the bulk of available services from the private to the public sector. However, most IVF services are still mainly offered in private clinics. Government forecasts banked on a gradual reduction in the proportion of IVF cycles performed in private clinics from 51% in 2010–2011 to 41% in 2012–2013, but according to MSSS data, this proportion remained fairly stable at approximately 70% in 2011–2012 and 2012–2013.

The concentration of tertiary clinics in Montréal inevitably leads to accessibility problems for people living elsewhere in the province. Not only are waiting periods for access to services longer, but even the care process itself entails logistical problems for people in regions that are less well served. Indeed, IVF-related treatments take place over several weeks and require close interactions with health professionals as well as a number of specialized procedures and examinations at specific points in the cycle. Distance from services accentuates the impact of treatments on patients’ personal and professional lives.

Before the program was launched, the MSSS had requested an assessment of the needs in each region. According to estimates obtained in late 2009, approximately 2,800 IVF cycles were required on the Island of Montreal, 1,000 in Québec City, 2,100 in Montérégie, and 2,100 in Laval and the Lanaudière and Laurentides regions combined. The government set a benchmark for the volume of services public assisted reproduction centers would provide once they are up and running. Discussions are underway between the MSSS and a number of regional stakeholders with a view to setting up secondary care clinics in Baie-Comeau (Côte-Nord), Rimouski (Bas-Saint-Laurent), and Lévis (Chaudière/Appalaches), as well as in Abitibi/Témiscamingue. Other regions have also been approached, including Gaspésie/Îles-de-la-Madeleine, and Montérégie.

According to MSSS data on funding earmarked for establishing assisted reproduction centers in hospitals, a total of $15,153,247 has been authorized to date for secondary and tertiary care centers. Depending on the case, funding has been allocated for capital expenses, equipment, or both. Since the program was launched, the government has thus invested substantial amounts on setting up specialized assisted reproduction clinics in university teaching hospitals and to a lesser extent in regional hospitals.
Some stakeholders have expressed their disagreement regarding the amounts spent on these centers and question whether the government should continue setting up public centers. They allege that the growth in demand since the program was launched has slowed down and is already leveling off to a point where it can be handled by existing clinics. Meanwhile the private sector has developed further. Certain clinics invested considerable amounts to increase their capacity after the program was launched. Since a single center, in Québécois city, has a waiting list, with wait times of six to nine months for IVF, existing services can be said to meet current demand in terms of volume, although not in terms of regional accessibility.

The Commissioner found access inequities not only from a regional but also from a financial perspective, given the additional fees charged in private clinics. These inequities undermine the social acceptability of the assisted reproduction program. Regional availability of services is directly related to the distribution of services between the public and private sectors. Most IVF services are still provided by private clinics, and the gap between the public and private sectors is widening. The situation is not evolving the way the government would like.

The Commissioner also took note of the questions raised regarding the relevance of developing the public sector when existing services seem to be able to meet the demand at the moment. He recognizes that a substantial portion of the expertise in the field is in the private sector and that it is legitimate for private clinics to demand a significant share of the market given the investments they made at the request of the MSSS when the program was launched. However, the current situation hinders the potential development of expertise in the public sector and allows the private sector to have its pick when recruiting newly trained professionals. If this trend continues, one could see the private sector dominating the market and over time, the government having less power to negotiate and control expenses.

The academic sector must also be strengthened to maintain the expertise it needs to train professionals, provide highly specialized, supraregional services, and support other levels of care in integrated university health networks. The Commissioner underscores the importance of developing a strong public sector and ensuring equitable access to ART services in the regions.

Service planning needs to be improved to take regional needs into account and strike the desired balance between the public and private sectors. This objective can be achieved through the granting of licences for both secondary and tertiary services. Currently, a permit is required to set up a tertiary care clinic, and a comparable approach could be taken for secondary care clinics. Up till now, a minimal volume of activity per clinic has been targeted, but it would be possible to set both minimum and maximum volumes and to make permit renewals and
reimbursement, for as many clinical activities as allowed, contingent upon targets being met. This approach provides flexibility over time and allows for planning to be adjusted, based on needs and the public and private sectors’ capacities for providing services. The preferred option is thus to manage the supply of services rather than to control or guide demand as would be the case with a one-stop access to the program.

Human resource planning and training must be consistent with regional planning. For example, most fertility specialists have been trained outside the province, and the Collège des médecins du Québec does not recognize a subspecialty in reproductive endocrinology and infertility, although regional plans for medical staffing (PREM) in the area of fertility are used to manage the distribution of these specialists. As for embryologists, the planned training program has still not received funding and no job title has been created.

**Commissioner’s Recommendation**

2. Promote more equitable access to assisted reproduction services in Québec’s regions by issuing secondary and tertiary care permits based on regional planning and the desired balance between public and private sector services.

**Recommendation 3: Improve Control over Program Costs**

The assisted reproduction program is a major investment for Québec. Québec’s Conseil du trésor earmarked $30.32 million for the program in fiscal year 2010–2011 when the program was established. According to the government’s forecasts, the total cost of the program would increase to more than $43 million in 2011–2012 and more than $47 million in 2012–2013.

However the demand for ART services has turned out to be greater than expected: the number of IVF cycles performed in 2012–2013 exceeded the anticipated number of cycles by nearly 50%. According to the report on the application of the Act respecting clinical activities and research related to assisted procreation tabled by the Minister of Health and Social Services in the National Assembly in October 2013, the program’s operating budgets also exceeded forecasts, totalling more than $60 million in 2011–2012 and over $61 million in 2012–2013. Predicted 2013-2014 costs for secondary and tertiary services officially rose to nearly $70 million.

Briefs submitted to the Commissioner indicate that these cost overruns are caused by a number of factors. It was mentioned that the amounts spent on IVF
are 11 times higher than initially planned ($43 million rather than $3.8 million). Such overspending cannot be explained solely by the 50% increase in demand. This is sufficient reason to examine the reimbursement terms for various procedures and to check whether billing modes are in line with the reimbursement terms initially planned. The amounts spent on setting up assisted reproduction centers were also higher than foreseen.

The information the Commissioner received suggests that the amounts earmarked for technical costs, fees, and infrastructure investments are excessive. Those active in the field of assisted reproduction also complained that funding arrangements are not the same for the public and private sectors. They see this as unfair. In reality, funding for assisted reproduction differs between the public and private sectors in many regards. For example, investments are covered by clinics in one sector and not the other and private clinics charge additional fees to patients and must pay all their staff.

Considering the various issues raised about program funding as a whole as well as funding terms and mechanisms, the Commissioner feels that greater transparency is required. The government must set up means for analyzing and regularly monitoring expenditures for the various budget items. Studying the breakdown of budget items will foster greater transparency and allow for targeted adjustments to improve performance.

The Commissioner’s recommendations on limiting access and prioritizing techniques are likely to generate certain savings. Limiting access based on predicted success rate, the intended mother’s age, and existing children, combined with measures restricting reimbursement of IVF to a single child and the judicious use of IVF would save approximately 20% according to a conservative estimate. Despite these potential savings, the program still represents a major investment in a context where other healthcare priorities and needs are not being met. Priority allocation of resources to this program does not have unanimous support, and in many people’s opinion this decision should have resulted from a greater consensus. The differences in opinion about public funding of the program have been clearly demonstrated by surveys conducted by the Commissioner and others. Members of the Consultation Forum also weighed in on the subject, as the following excerpt from their deliberations attests:
“This program raises . . . major questions about Québec’s societal choices: Can Québec afford its choices? If we offer free assisted reproduction services, what other services will suffer as a result? . . . To ordinary citizens the fact that such a program has been established in the current economic situation without more thorough reflection is very worrying, and even horrifying, according to certain members.”

Consultation Forum deliberations, September 2013

Given limited financial resources and the fact that the assisted reproduction program does not address vital healthcare needs, the Commissioner recommends that a financial contribution for IVF services should be required, based on family income. According to a number of people interviewed in various clinics, couples have complied less seriously with their management schemes since the introduction of free services, which reduces the odds of success. Requiring a financial contribution from the intended parents would increase their personal commitment to the care provided and to their parenthood plans. Furthermore, the notion of a financial contribution was approved by 67% of the population according to a survey conducted for the Commissioner. This position was also strongly defended by Consultation Forum members, who saw it as a matter of fairness. While the previous recommendations were aimed at ensuring the program’s sustainability, the idea of charging a reasonable fee for IVF in an era of budget constraints is intended to enhance its social acceptability. In fact, for the program to be viable, it must be socially acceptable.

Even though this option confers certain benefits, its implementation presents a number of challenges, including how the payments should be levied and managed. The cost of administering these charges must not exceed the resulting savings and if this measure is implemented, the fees should not hinder access to the program on the sole basis of people’s revenues.

Despite the thinking that will have to go into implementing such a measure, the Commissioner firmly believes that it is worth pursuing in the current context. However, it will be important to make sure this option is feasible and that its implementation does not conflict with the societal values and legal frameworks prevailing in Québec and Canada.
Commissioner’s Recommendations

3.1 Make all program costs public, broken down by category: technical costs, fees, drugs, and infrastructure.

3.2 Periodically review technical costs and adjust amounts earmarked, if necessary, as practices and actual costs evolve.

3.3 Establish the parameters governing the financial contribution to be charged to intended parents, based on income.
3.2 **Build program capacity for evaluation, reflection and action**

**Recommendation 4: Evaluate the impact of assisted reproductive technologies on the health of women and children**

Even before the program was launched there were plans to create a registry to monitor the assisted reproduction program and its impact on the health of women and children. Nearly four years later, a proper registry has yet to be put into place. Most of the people the Commissioner consulted complained about this situation, and numerous briefs mentioned the need to set up a registry to monitor long-term clinical data.

The MSSS set up the ProAssis-L08 system after the program was launched. Due to its limited scope, this system does not meet international standards, does not allow to accurately calculate success rates, and is out of phase with respect to current assisted reproductive technologies. One of its major weaknesses is the lack of standardized data entry. In parallel with the ProAssis-L08 system, assisted reproduction centers compile data on their patients in another system that enables them to transfer the data to the Canadian ART Register (CARTR). Clinics contribute on a voluntary basis to this databank, which was created 12 years ago and has been administered up until recently by the Canadian Fertility and Andrology Society (CFAS).

In 2012 CFSA arranged with BORN Ontario (Better Outcomes Registry and Network) to host CARTR data on the BORN server. This allows CARTR to take advantage of the BORN data system’s registry status. This status enables assisted reproduction data to be linked to data on subsequent health care utilization by women who have conceived through assisted reproduction as well as their children. BORN also has the necessary expertise and resources to perform more sophisticated analyses on the data and systematically check data entered by clinics, thus enhancing quality assurance.

More recently, the MSSS undertook to improve how it collects assisted reproduction data. To make the ProAssis-L08 more effective, MSSS signed an agreement in June 2013 to acquire a new clinical data management application. It seems, however, that discussions are still underway about what data will be entered and transmitted using this software. Furthermore, the application will be installed only in clinics from the public sector. Therefore the current obstacles hindering adequate data collection to properly monitor activities and ensure adequate program accountability are not likely to be resolved any time soon.

At the same time, the MSSS has started drawing up a surveillance plan for assisted reproduction. Proposed data sources include a new data collection
system on ART procedures, with data probably supplied by the ProAssis-L08 system, and other existing MSSS and RAMQ databases, including records of live births, deaths, stillbirths, hospital stays (MED-ECHO), fee-for-service procedures, and tumors. Considerable work has already been done to justify the choice of indicators. In the draft surveillance plan for medically assisted reproduction, special attention was paid to the main assisted reproductive technologies, obstetrical history, and obstetrical and maternal complications. Apart from basic data related to births, few variables that would enable monitoring of longer-term effects on children have been targeted for inclusion in the data system. The MSSS plans to assume responsibility for analyzing the collected data and publishing regular reports. There are no plans for using the data for research.

Ongoing monitoring of long-term clinical and psychosocial outcomes is required because of a number of factors, including the state of knowledge on the risks associated with assisted reproduction, the potential for prenatal risk factors having very long-term impacts, and the rapid changes in ART practices. The scientific literature clearly indicates that obstetrical risks and certain other risks for women and children are higher with assisted reproduction than spontaneous conception. This was also shown in Chapter 2. The role infertility, advanced maternal age, and assisted reproductive technologies play in causing other complications is uncertain. The lack of reliable, up-to-date information on this program and its impacts has several negative consequences for the government. Indeed, the government is accountable not only for resources allocation but also for program results. Therefore, it must ensure that quality assurance mechanisms are in place and that the risks associated with the procedures it funds are minimized.

After almost four years and considerable investments, the Commissioner notes that the government still lacks the necessary tools to evaluate the program and its impacts. The members of the Consultation Forum were outraged at this lack of resources and tools:

Considered “inconceivable” or “scandalous” by some, the lack of data and a birth registry is unacceptable in their opinion, especially given the risks associated with assisted reproduction and the resulting pregnancies, both for the child and the mother. . . . The lack of evaluation and monitoring tools is . . . especially worrisome . . . given that the program’s impact and consequences are real and must imperatively be documented.

Consultation Forum deliberations, September 2013

It is essential to continuously monitor the costs and risks associated with assisted reproduction in order to inform and be accountable to the public. The

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9 According to the ministerial authorities consulted, a parallel system may be put in place because the legal framework for health surveillance is different from that for program accountability.
Commissioner is therefore not at all surprised at the indignation expressed by a number of stakeholders, including members of the Consultation Forum. He recognizes that the MSSS has made substantial efforts. However, these efforts have not resulted in access to valid data.

The Commissioner considers that Québec must put in place 1) the necessary means to compile detailed data on ART procedures in a database or registry equipped with quality control processes, 2) a reliable way of linking these data with clinical outcomes on ART users, and 3) ways of regularly analyzing all relevant data with the required multidisciplinary expertise. Ideally, the registry should contain data not only on procedures and drugs administered for IVF, but also on ovarian stimulation without IVF and artificial insemination.

In a number of briefs submitted to the Commissioner, it was suggested that the registry should contain data on the first few years of life of babies conceived through assisted reproduction in order to trace all children thus conceived and monitor their development. The added value of being able to compare the information with data compiled elsewhere, by CARTR-BORN for example, was also stressed.

The following points should receive due attention in implementing the planned monitoring system:

- Both planned implementation phases, namely the creation of an ART database and the process of linking it with other medico-administrative databases to monitor relevant health outcomes should be given priority by ministerial authorities and quickly deployed.
- The database should be designed for various purposes, including monitoring practices and health surveillance.
- All public and private assisted reproduction centers should be obliged to enter requested data in the database in real time.
- The system should establish a link between data on mothers and children for all newborns, including multiple births.
- The database should be designed such that the data can be analyzed by complete IVF cycle, including the transfer of frozen embryos, and by individual woman.
- The database should contain information that is detailed enough to be compared with data compiled in systems elsewhere.
Commissioner’s Recommendations

4.1 Set up, as a matter of urgency, a centralized database permitting longitudinal monitoring of assisted reproduction activities and evaluation of the health impacts on mothers and children.
4.2 Use these data for health surveillance and continuous quality improvement purposes.

Recommendation 5: Strengthen Program Governance

The Réseau québécois de procréation assistée was created in fall 2009 to serve as an advisory committee and contribute to the governance of the assisted reproduction program. Its mission is to issue advice to ensure patients have access to safe, quality care within acceptable timeframes; follow up on current issues and developments in assisted reproduction; make recommendations on standards of practice, the organization of services, and the introduction of new technologies; facilitate networking and collaboration among all assisted reproduction centers; and propose a regulatory framework for research in the field. The objective is to help improve assisted reproduction and infertility prevention practices.

The Commissioner has received numerous complaints about how Réseau québécois de procréation assistée operates. Although the network is headed up by someone from outside the MSSS, it works closely with the ministry. According to some, this situation does not provide the network with sufficient leeway. The participation of actors directly involved in service provision seems minimal, and restricted to professionals working in hospitals. Some stakeholders have questioned the network’s legitimacy due to a perceived lack of knowledge about practices in the field. There appears to be a profound lack of trust on both sides. It should be kept in mind, however, that the network was not given the necessary means to produce evidence reviews, for example, and does not have access to statistical data on practices or on downstream services utilization to support its deliberations. These limitations regarding the network’s functioning mean that the additional governance mechanisms put in place to help the MSSS and the minister fulfill their responsibilities are not working.

The Commissioner deplores the limitations of the current oversight mechanisms and the lack of clear guidance. There is an urgent need to introduce monitoring and governance mechanisms in order to acquire a wide perspective on the entire field of practice and its development, identify unusual practices or phenomena, and follow the clinical, psychological, ethical, and social consequences of assisted reproduction, including long-term impact. In the field, the lack of mechanisms for standardizing practices has resulted in a diversity of
medical and psychosocial practices that could be accentuated by competition among clinics and potential conflicts of interest. The absence of clear directions on how to handle the ethical issues that arise in clinical practice was also brought to the Commissioner’s attention.

A number of countries have set up independent agencies to oversee ART practices. France’s biomedicine agency and the Human Fertilization and Embryology Authority in Great Britain are good examples. However, this solution seems less acceptable in Québec due to the current trend of streamlining government bodies.

Even if a relatively light governance structure is chosen, it must still be able to carry out a number of functions with regard to monitoring and evaluating assisted reproduction practices and reflecting on ethical issues. Given the array of concerns brought to the Commissioner’s attention, it is clear that a structure with the ability to monitor changes in technology, clienteles, and clinical and laboratory practices must be set up in order to develop a comprehensive, integrated perspective. With respect to technologies, among other things this structure should be able to monitor whether clinics are using approved technologies only, carrying out innovative practices or conducting research, whether the choice of techniques is influenced by funding arrangements, and whether incidents occur with certain procedures. A forum for reflection and dialogue on ethical issues is also required.

The Commissioner feels that even if an agency is unlikely to be created in the current context, the above objectives could be met by setting up a permanent multidisciplinary committee reporting directly to the minister, as well as an issue table on ethics. The committee should have the expertise, credibility, and means to instigate the necessary actions. The issue table on assisted reproduction ethics should be made up of stakeholders with expertise in this field.

Permanent Multidisciplinary Committee on the Development and Monitoring of Assisted Reproduction Practices

A number of existing bodies have responsibilities similar to those listed above. The Collège des médecins du Québec not only issues licenses to practice, but also has the duty to protect the public and monitor the quality of medical procedures by performing inspections and setting norms. The Institut national de santé publique du Québec (INSPQ) assumes health surveillance functions in other fields, so it could put its data management and analysis expertise to work in the area of assisted reproduction as well. It could also help develop indicators and quality standards for registries and databases. The Institut national d’excellence en santé et en services sociaux (INESSS) is tasked with conducting evidence reviews and developing practice guidelines for clinical and psychosocial activities.
The MSSS already acts as a regulator by issuing licenses and inspecting assisted reproduction clinics under the Act respecting clinical and research activities relating to assisted procreation. Numerous professionals in the field have demonstrated their commitment to improving practices by collecting data, which make it possible to compare success rates among clinics for example, and most support the notion of using such data to provide feedback to clinicians.

The Commissioner believes that all key players who can help improve the governance of assisted reproduction should be asked to participate and contribute. No single organization possesses all the required expertise, data, and tools. Therefore effective collaboration among these players is essential. Representatives from the Collège des médecins du Québec, INSPQ, and INESSS should sit at the same table with professionals in the field and representatives from RAMQ and MSSS. To ensure the committee’s expertise and impartiality, it is important that it be hosted by a body that is independent of the MSSS, such as INESSS. The committee should monitor the entire field of practice, whether in clinics or laboratories, and both the scientific and psychosocial aspects, with a view to continuously improving the quality and relevance of services. These responsibilities exceed those that an advisory committee to the MSSS such as the Réseau québécois de procréation assistée could take on.

When pooling expertise from such a relatively small community, it is impossible to avoid involving people who have conflicts of interests. Credibility requires expertise, but expertise involves interests. It is therefore important to establish transparent means for evaluating and managing conflicts of interest, to balance various types of expertise, emphasize competence and the capacity for collaboration over prestige and notoriety, ensure committee member turnover, and promote shared accountability to the public and the various health authorities.

**Issue Table on Assisted Reproduction Ethics**

The Commissioner’s consultations revealed that a number of professionals in the field would like more guidance from the MSSS on what direction to take and how to handle certain requests from their clients. The clinics’ ethics and interdisciplinary committees have said that they have faced difficult ethical issues but have no forum for discussing them with other professionals who face similar situations.

There is a widely expressed need for a community of practice in assisted reproduction ethics. The collective journey toward this much sought-after shared vision could be supported by pooling experience acquired on the ground. Collective wisdom could be developed by discussing various cases professionals have faced. The community of practice could take the form of an issue table on assisted reproduction ethics made up of members of the various ethics and
multidisciplinary committees active in the field in order to pool their combined experience. For this community of practice to materialize, however, its activities must be supported by a permanent body such as the Commission de l’éthique en science et en technologie.

The creation of an issue table on assisted reproduction ethics would permit more in-depth reflection on complex subjects. The priority issues the table would need to address are listed in Section 3.5 on ethical issues and societal choices. This table would thus not only equip ethics committees and professionals active in the field to handle difficult situations—and therefore better protect patients and future children—but also permit more in-depth deliberations on all these issues within the Québec context.

**Commissioner’s Recommendations**

<table>
<thead>
<tr>
<th>5.1 Establish a permanent multidisciplinary committee on the development and monitoring of assisted reproduction practices, which will replace the Réseau québécois de procréation assistée, and invite the Collège des médecins du Québec, Institut national de santé publique du Québec, Institut national d’excellence en santé et en services sociaux, and professionals in the field to take part.</th>
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<tr>
<td>5.2 Set up an issue table on assisted reproduction ethics, which could be hosted and supported by a permanent body such as the Commission de l’éthique en science et en technologie.</td>
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Recommendation 6: Ensure the relevance and integrity of research relating to assisted reproduction

Québec researchers are active in the field of assisted reproduction, particularly on topics related to new drugs, culture media for embryos, effectiveness of new techniques, and causes of infertility. Some forms of research in this field, whether conducted in the public or private sector, are funded primarily by private sources such as pharmaceutical companies or manufacturers of technologies and tools used in assisted reproduction. Although this is not unique to assisted reproduction and also applies to drug development, dental medicine, and health technologies, it does raise certain concerns.

With regard to the advancement of knowledge, some areas of research, although essential, are likely to be of less interest to private funding sources. Examples include longitudinal or epidemiological studies on the health of mothers and children and research on certain psychological aspects associated with infertility and assisted reproduction. Public funding by Canadian and Québec granting agencies is therefore crucial for these types of research.

One of the normative documents governing research on humans in Canada, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, specifies that any research project involving human beings or human biological material, including reproductive material, must be submitted to a research ethics committee for approval. One of the challenges in assisted reproduction is distinguishing research—or practices that should be researched—from innovative practices, which are not subject to the same level of oversight. Stakeholders the Commissioner consulted mentioned the possibility that not all research on assisted reproduction is being referred to research ethics committees.

Therefore, in some circumstances, research may still be conducted without sufficient oversight. This could be the case for privately funded work using gametes or embryos conducted in the private sector by researchers not affiliated with a university, for instance. The delicate nature of this type of research requires adequate supervision, including an assessment by an independent research ethics committee with expertise in assisted reproduction.

Regardless of the research setting, research ethics committees must be given the necessary resources to perform their evaluations at the appropriate time and in the appropriate manner. Training should be provided to professionals in the field on the concept of conflicts of interest and on how to determine which activities necessitate organized research projects. Lastly, it is crucial that research ethics committees, whether institutional or private, remain independent.
Commissioner’s Recommendation

6. Specify in a regulation on assisted reproduction that all research in this field, whether conducted in the public or private sector, must be overseen by an independent research ethics committee with the necessary expertise in assisted reproduction.

3.3 Ensure the Quality of Care and Services

Recommendation 7: Improve the organization and continuity of services

Given that ART services mainly developed on the margins of the health and social services system, close ties are lacking between these highly specialized services and less specialized services in obstetrics/gynecology, endocrinology, and family medicine. The tiering of services, progressively introduced since 2004, has meant that specialized services are provided in university teaching hospitals, services organization is managed according to the MSSS-ASSS-CSSS hierarchy, and access to tertiary care is coordinated by integrated university health networks. However, this logic has not applied to the field of assisted reproduction. As a result, private clinics that offer tertiary ART services are not part of a system that fosters a sense of responsibility towards primary and secondary care.

Although the Act respecting clinical and research activities relating to assisted procreation broadly defines assisted reproduction activities, Section 16 of the Regulation respecting clinical activities related to assisted procreation specifies which services can be provided outside designated “centers for assisted procreation.” Among the other initiatives related to the tiering of services, two types of highly specialized services have been recognized, namely assisted reproduction in cases of viral risk in one of the partners and preimplantation diagnosis.

Despite the government’s efforts on tiering of services, there are still problems with respect to continuity of care. The Commissioner received a number of comments indicating that collaboration between the various services is less than optimal. In many cases, laboratory tests conducted by primary or secondary level services are not taken into account or are automatically repeated by tertiary care clinics. A certain level of confusion seems to arise when patients of private clinics have their tests done in a hospital or vice versa.

Attending physicians often do not receive information on ART protocols and specialized clinics cannot always be reached when complications arise outside normal business hours, although some clinics do have 24 hour telephone lines.
The Commissioner learnt that it can be difficult to arrange healthcare service corridor agreements, but it is impossible to say whether a lack of interest on the part of hospitals or other obstacles are at stake.

The distribution of supraregional responsibilities, particularly with respect to preimplantation diagnosis, is questioned by certain stakeholders and leads to long delays for some couples. Some point out that the reorganization of these services has led to unacceptable wait times as well as parallel service arrangements. Preimplantation diagnostic services are indeed offered by certain private clinics for an additional charge and the tests are analyzed outside Québec.

According to comments received, many primary care professionals are ill informed about the program and available services and are slow to perform infertility assessments. In principle, family doctors should perform a basic male and female infertility workup before referring their patients to secondary care in infertility endocrinology or obstetrics/gynecology. With regard to patients who consult their family doctors or obstetricians/gynecologists, approaches and care trajectories appear to vary considerably. Some doctors prescribe diagnostic tests or hormonal treatments, while others offer very little in the way of solutions to their patients.

The lack of clarity about stakeholder responsibilities regarding assisted reproduction at the various levels of care has numerous consequences. The lack of communication and effective links between levels of care on the one hand, and between public and private services on the other, causes inefficiencies for the system in terms of how tests are used, and patients are confronted with repeated referrals and delays in infertility testing and ART treatments. Furthermore, ART procedures performed in primary and secondary care such as ovarian stimulation and artificial insemination, which are not overseen by the program, may involve health risks for women and children. These risks are currently hard to quantify because it has not been possible to document the number of multiple pregnancies resulting from ovarian stimulation prescribed in primary or secondary care. The failure to pay enough attention to primary and secondary care practices may increase risks for women and children and make the program’s multiple-pregnancy reduction targets more difficult to reach.

The Commissioner believes that the MSSS must step up its efforts to clarify roles and responsibilities at each level of care by drawing on the combined expertise of the permanent multidisciplinary committee on the development and monitoring of ART practices, yet to be created. The MSSS must also rally professionals to the task of creating a functional tiered network of assisted reproduction services. Lastly, the information on roles and responsibilities should be conveyed to professionals working at the various levels of care, and additional training provided, as needed.
Commissioner’s Recommendation

7. Finalize the clarification of roles and responsibilities of all professionals providing assisted reproduction services with respect to all techniques, including ovarian stimulation, artificial insemination, and IVF, in order to minimize the risks associated with assisted reproduction.

Recommendation 8: Improve support for patient decision-making

The decisions facing people who start infertility treatments are particularly difficult to make given the psychological, social, cultural, and ethical aspects involved and their impact on the future child. The situation is highly emotional, and patients have to absorb and understand a considerable amount of technical, clinical, and psychosocial information. So it is important to provide validated, up-to-date information at various points in the process in order to achieve truly informed consent. General consent obtained at the beginning of the process is not sufficient.

The Regulation respecting clinical activities related to assisted reproduction specifies what information patients should receive in order to give their free and informed consent. This information includes adverse effects, risks, nature of the procedures, success rates, etc. According to the testimonies received and the Commissioner’s consultations, patients are not always optimally informed. The Regulation’s provisions about what information patients need to have in order to give free and informed consent should also be updated. For example, it is important to provide information on drug costs, accessory fees, and care pathways. Patients demanded a better access to psychological support and did not always appear to be well informed about existing psychological support services.

One of the difficult choices facing parents who start IVF treatments concerns the disposal of surplus frozen embryos once their family is complete. The options they are confronted with are either having the embryos destroyed or donating them for research or to other intended parents. Parents need to be supported when making this decision. Their consent should be more detailed with regard to the various possibilities of each option and should be renewed at different times during the process. For example, it is important to make a distinction between the various types of research involving embryos as the parents may find certain types more acceptable than others.

Given the number and complexity of the issues and potential long-term implications for the various people involved when a third party donates gametes, the Commissioner feels that counseling specially tailored to these patients’ situations is required, followed by specific consent. Psychologists are recognized
as having the necessary expertise and should ideally be involved. Guidelines specific to each situation were designed by a committee from the Canadian Fertility and Andrology Society (CFAS).

To standardize counseling practices across fertility clinics, counseling should be included in fertility clinic protocols and should no longer be governed by in-house policies. The Regulation respecting clinical activities related to assisted procreation should specify that counseling is mandatory rather than simply a recommended practice whenever treatment involves donor gametes.

### Commissioner's Recommendations

8.1 Amend the Regulation respecting clinical activities related to assisted procreation

- By adding information that must be provided to the people involved, including information on care pathways, accessory fees, and patients’ responsibilities with regard to the assisted reproductive technologies’ success
- By specifying that appropriate counseling must be provided to all parties whenever treatment involves donor gametes, in order to ensure informed consent

8.2 Provide ongoing support for intended parents in clinics

- To enable informed, validated, and up-to-date consent at key points in the process
- To support their decision-making right from the beginning of the IVF process, notably by clarifying the consequences of the choices they face with respect to surplus embryos
3.4 **Respond to Psychosocial Issues**

**Recommendation 9: Organize psychosocial assessments of intended parents**

Assisted reproduction clinics face a number of situations presenting unique ethical issues, which staff do not always know how to handle. For example, prospective patients may have a serious debilitating illness, a major intellectual disability, or a history of drug or alcohol use, or they may be very young or very old, or incapable of meeting the physical needs of a child. Some circumstances may entail potential psychological or physical risks for the future child.

Given these existing and potential problems, many of the people consulted called for stricter oversight of the assisted reproduction program, comprising a psychosocial assessment that might resemble that required for adoption. This was the position of the Consultation Forum members:

[The members] feel that an initial, mandatory assessment of psychological and parental capacity should be required of anyone wishing to use ART services. The assessment should be thorough but adapted to each case.

Consultation Forum deliberations, September 2013

The motivation behind this suggestion is mainly to protect the future child. It would obviously be a mistake to generalize about psychosocial risks to children conceived through assisted reproduction and to question the parental capacities of most people. Nonetheless, the government does have a specific responsibility regarding assisted reproduction and its consequences, particularly with regard to the future child. By allowing universal access to services under the program and allocating public resources to it, the government has *de facto* a responsibility with regard to these children’s existence.

It is important to stress the shared responsibility of all parties regarding birth of children conceived through ART, by the very fact that this conception was assisted. The parents’ responsibility for the child’s well-being needs to be reaffirmed, but so does that the responsibility carried by the clinics throughout the process. In the United Kingdom, all intended parents must complete a self-administered questionnaire in the best interests of the child. The form includes questions about their medical and psychosocial history (mental health problems, violence in the nuclear family, alcohol or illicit substance abuse, genetically transmitted diseases, and interventions by child protection authorities).

Although some clinics in Québec ask patients to complete in-house questionnaires on their medical histories, these forms are not standardized, vary in content, and are not always used. They should ideally be standardized and should include psychosocial questions. If the future child is found to be at high risk, the health professional should request a more in-depth, independent
assessment performed outside the clinic. At any time during treatment, the doctor, nurse, or psychologist should be able to request an assessment to determine the intended parents’ parental capacities and the seriousness of their parenthood plans.

A problem remains with respect to the definition of best practices in assisted reproduction. INESSS could therefore be asked to develop guidelines in cooperation with the professional orders concerned (mainly of psychologists and social workers) and child protection specialists.

**Commissioner’s Recommendation**

9. Amend the regulatory framework governing assisted reproduction in order to better protect the wellbeing of the future child by specifying the following points:

- Anyone requesting assisted reproduction services must complete a form about their psychosocial history.
- Professionals at assisted reproduction clinics must refer intended parents for a psychosocial evaluation if at any time during the provision of services they have serious cause to suspect potential social or psychological risks to the future child.
- Psychosocial assessments by referral must be performed independently of the clinic at the expense of the individuals concerned.

**Recommendation 10: Limit shopping around for services**

The Commissioner has received reports that some people who are denied treatment at one clinic may visit a series of clinics until they obtain the services they seek. Such situations of abuse may arise whether the refusal is based on psychosocial concerns or a low probability of success. A number of people, including health professionals, have complained of incidents that they themselves have witnessed but felt unprepared to handle.

This type of situation arises both because services are free, which to some people means they have a right to assisted reproduction, and because the lack of clear guidance and criteria makes it difficult for clinic staff to deny access to these services. Furthermore, there is currently no way of following patients through the system.

The Commissioner believes that it is critical to be able to follow patients throughout the assisted reproduction process, starting from when they first
register at a clinic. They should be systematically registered in real time so that the information can be shared with other clinics, for example, in the event the person is denied access to services for medical or psychosocial reasons. This measure should not prevent the individual from seeking a second opinion.

**Commissioner's Recommendations**

10.1 Provide for real-time registration of anyone visiting a clinic for services in a centralized database accessible to all clinicians providing assisted reproduction services.

10.2 Record all data on patient trajectories in the database, including number of treatment cycles, referrals for assessment of parental capacity and seriousness of their parenthood plans, and any refusals to provide treatment due to medical or psychosocial reasons, if applicable.

**Recommendation 11: Recognize the legitimacy of the search for one’s origins by equitably reimbursing the cost of gametes**

Under the Québec assisted reproduction program, the RAMQ has signed agreements with three Canadian sperm banks that are supplied from the United States. Only sperm straws from these banks or from private Québec banks are reimbursed, and reimbursement applications are eligible only if the sperm straws are from anonymous donors. Furthermore, only one straw at a time is reimbursed. This means that it is impossible to store straws in order to have several children from the same donor and thus brothers and sisters who are related. According to the Commissioner’s consultations, an increasing number of couples and single women pay about $700 per straw out of pocket to use sperm from an open-identity donor rather than be reimbursed for sperm from an anonymous donor. The government currently pays $600 per anonymous sperm straw.

There appears to be a strong trend towards recognizing the importance of children’s origins, both in Québec and internationally. Arguments related to the rights of children to have access to information regarding their origins are also evoked, and policies on the anonymity of gamete donations have been amended in recent years in a number of countries.

In principle, gamete donation is anonymous in Québec, as information on assisted reproduction is to be kept confidential. In reality, however, gamete donation practices vary from clinic to clinic. Some give intended parents the option of using a donor from Québec, or elsewhere, who has agreed to have their identity revealed, while others provide access to anonymous donations only. Parents are not always informed of these differences in practices.
Québec’s position on the anonymity of gamete donation has been strongly criticized in view of the interests of the child, both in Québec and internationally. During the Commissioner’s consultations, a number of people also called for an amendment to the Civil Code of Québec to ban donor anonymity in the context of artificial insemination and IVF. The family law advisory committee tasked by the justice minister with reviewing Québec family law is currently examining these issues.

Other issues related to gamete donation were brought up during the Commissioner’s consultations. With the launch of the assisted reproduction program, demand for donated gametes has increased considerably. The lack of publicly-operated gamete banks in Québec, along with the Canadian prohibition on payment of donors, has encouraged reproductive tourism, particularly with respect to eggs. Some Canadian banks that have been offering frozen sperm for several years are now able to provide frozen eggs as a result of recent technical advances. While the purchase of frozen sperm from other provinces is covered under the Québec program, the purchase of eggs is not, which raises the issue of fairness.

Because of these issues, a number of people have demanded that public gamete banks be set up in Québec and managed by an organization with the required expertise, such as Héma-Québec. However, the Commissioner feels that it would be better to wait for the family law advisory committee’s position on the anonymity of gamete donations before considering whether to set up a public gamete bank, as its operational modalities could be affected by the Committee’s conclusions.

Given the need for collective and legal reflection on the removal of donor anonymity, and the increasing recognition of the right of adopted children and those conceived through assisted reproduction to information about their origins, the Commissioner believes that, at the very least, gametes from both anonymous and open-identity donors should be equitably reimbursed. Conversely, the government could limit the number of sperm straws it reimburses per woman for both IVF and artificial insemination, regardless of whether sperm donors are anonymous. This measure would provide equitable access at no additional costs.

**Commissioner’s Recommendations**

11.1 Reimburse the same amount for sperm straws from open-identity donors as for those from anonymous donors.

11.2 Limit the number of sperm straws reimbursed per woman.
3.5 Deliberate on Ethical Issues and Societal Choices

Recommendation 12: Put surrogacy and the fate of surplus embryos on the agenda

A number of ethical issues have been brought to the Commissioner’s attention. The social acceptability of the assisted reproduction program, fair and reasonable allocation of resources, equitable access to services, the provision of quality services, inherent risks, children’s rights to information about their origins, assessment of parental capacity, and informed consent have already been addressed in the Commissioner’s previous recommendations. Other issues inherent to the use of assisted reproductive technologies that do not have a direct impact on the program’s performance were also raised. Among these, the Commissioner feels that the ethical and psychological implications of some gamete donation practices such as double, intrafamilial, direct, cross, and reciprocal donations, should be examined in more depth. However, surrogacy and the fate of surplus embryos should be studied on a priority basis by the issues table on assisted reproduction ethics (Recommendation 5).

Fate of Surplus Embryos

The Commissioner was made aware of the fact that numerous frozen embryos are accumulating in assisted reproduction clinics. Some of these embryos will be used by intended parents for future attempts at assisted reproduction or to complete their family. Once this process is finished, the embryos remaining in the bank are classified as surplus embryos. The accumulation of frozen embryos is unanimously considered to be a problem, particularly if the parents have not indicated what they want done with their embryos.

If the clinic has not heard from the intended parents for five years, the Regulation respecting clinical activities related to assisted procreation specifies that “a centre for assisted procreation may conserve, donate, transfer or dispose of those persons' gametes or embryos in a manner that is acceptable in terms of ethics and recognized by the Minister.” A number of problems arise as a result of the wording of this section. Indeed, the regulation leaves it up to the clinicians to decide what happens to surplus embryos, but that responsibility should not be theirs.

Section 25 of the regulation specifies the conditions under which an assisted reproduction center may transfer embryos or gametes to another center for research or clinical use with the parents’ consent. This section has to do with the management of embryo banks, which are banks of biological material, although no appropriate framework for setting up such banks is provided for. Formally setting up embryo banks requires a framework that addresses a number of considerations, including governance structure, terms of access and embryo transfer, methods of conservation, confidentiality, and ownership, and closure of
the bank. Furthermore, banks should be differentiated based on their use, i.e. clinical or research.

The difficulty healthcare professionals and intended parents have in making decisions about surplus embryos is proof of the social and personal dilemma we currently face. The production, use, and storage of embryos raises ethical issues related to the special status ascribed them. This is not just any biological material, and the Commissioner feels that, as a result, they deserve special consideration.

A societal debate must be encouraged to bring about broader awareness of the choices made in the field of assisted reproduction and their social implications. The issue table on assisted reproduction ethics could study the question of surplus embryos in order to guide amendments to the sections of the regulation that cover these issues and inform a societal debate on the subject.

**Surrogacy**

Surrogacy is practiced in and outside of Québec. Given the ethical issues it raises, it cannot be ignored even though it is still not very common. The term surrogacy refers to any situation where a woman undertakes to bear a child, not with the intention of keeping it and taking responsibility for it as a mother, but rather with the intention of giving it at birth to the individual or couple who engaged her services, whether free of charge or for payment. There are two main categories of surrogacy: either the woman both provides the egg and bears the child or she only bears the child.

According to Québec law, a woman who gives birth to a child is legally its mother. Therefore, intended parents in surrogacy cases must adopt the child to obtain legal guardianship at birth. However, as surrogacy contracts are absolutely null under Section 541 of the *Civil Code of Québec*, the result of the adoption process is uncertain. In 2004, Canada passed the *Assisted Human Reproduction Act*, which permits surrogacy contracts under certain conditions, namely that there can be no payment for surrogacy. The practice of surrogacy is thus legitimized by federal law, which according to the Commissioner’s consultations creates a certain confusion on the part of professionals in the field as to whether surrogacy is permitted in Québec or not.

Physical and psychological risks for surrogate mothers and their children are a major concern and have been well documented. The physical risks are associated with assisted reproductive technologies and with gestation. The most commonly documented psychological risk is related to the fact that the surrogate mother must give up the child to the intended parents, which may cause her grief and suffering. The feeling of abandonment the child may feel was also raised. Questions related to women’s reproductive autonomy, human dignity, the
instrumentalization of individuals, and the commercialization of the human body are other issues involved.

According to those consulted by the Commissioner, children born of surrogate mothers also run other risks, including being perceived as a consumer good that can be bought and sold. Due to the complexity of establishing the filiation of a child born under a surrogacy agreement, the child may find itself without a legal mother or father. Such situations have arisen when the intended parents refused to adopt.

Revising the framework governing surrogacy requires amending the Civil Code of Québec, a process that falls outside the scope of the assisted reproduction program. In addition, a committee set up by the minister of justice is currently working on revising Québec’s family law, including the situation of surrogate mothers.

Given the risks inherent to surrogacy and the evolution of practices in this regard, the Commissioner feels that in order to minimize risks it would be preferable to address the issue of surrogacy rather than ignore its existence. Members of the Consultation Forum expressed the following wish:

... that a societal debate take place before measures are taken to deal with the issues this practice raises ... and many believe that the Commissioner should convey the need for in-depth reflection on the topic of surrogacy. What do we consider acceptable for our community and into what kind of society do we want our children to be born? Furthermore, members clearly object to the instrumentalization and commercialization of the human body and they consider it essential that surrogacy should not involve compensation.

Consultation Forum deliberations, September 2013

Therefore, the issue table on assisted reproduction ethics should examine this topic on a priority basis as soon as the family law advisory committee has released its findings.

Given the wide divergences in public opinion, these ethical and legal reflections should feed into a societal debate on surrogacy. This debate should be entrusted to a competent body in the field of ethics and citizen deliberations.
**Commissioner’s Recommendations**

12.1 Have the issue table on assisted reproduction ethics address two priority themes:

- The disposal of surplus frozen embryos with a view to revising sections 24 and 25 of the *Regulation on clinical activities related to assisted procreation* within a year
- The practice of surrogacy in order to thoroughly examine the ethical implications of the recommendations issued by the family law advisory committee

12.2 Adopt a moratorium on the disposal of embryos for which parental consent has not been obtained while sections 24 and 25 of the regulation are being reviewed.

12.3 Launch a societal debate on the social acceptability of surrogacy based on legal, ethical, clinical, and social information.
Conclusion

The issues raised by Québec’s assisted reproduction program are so important that they could call the program’s very existence into question. Despite these issues, however, the program does have positive impacts. The Commissioner feels that due to these positive effects and the risks associated with keeping assisted reproduction on the margins of the health and social services system, the program should be maintained and improved, and that public funds should be better managed.

The Commissioner’s recommendations target a number of objectives:

- Ensure the program’s viability and acceptability by improving the reference framework, services planning, and control over program costs.
- Build program capacity for evaluation, reflection, and action through program governance tools and monitoring of clinical and research activities.
- Improve the quality of care and services, particularly with regard to information provided to the public and professionals, continuity of care, and cooperation between levels of care.
- Respond to psychosocial issues relating to reported abuses by putting the priority on the wellbeing of the children conceived through assisted reproduction.
- Deliberate on ethical issues specific to the field and foster a collective reflection and debate on societal choices.

The Commissioner believes that implementing the first five recommendations is essential in the short term if Québec intends to maintain its assisted reproduction program. They constitute the basic elements of a reference framework for the program and will make it possible to monitor practices, their evolution as well as the issues they raise.

In order to propose realistic and acceptable changes, it was important to document the context and to take into account the concerns expressed by citizens and stakeholders as regards the emerging issues, challenges, and implications of government objectives. In his detailed advisory report, the Commissioner relied heavily on testimonies from stakeholders and citizens and maximised the information that could be derived from available Québec data. The Commissioner wants to ensure thorough documentation of the issues and transparency with respect to the information obtained. With a view to knowledge transfer, much of the supporting material is available on the Commissioner’s website.
The best interests of the child have underpinned all the Commissioner’s recommendations and should spur all stakeholders to become involved in this issue, according to their responsibilities and the means at their disposal. Assisted reproduction calls for shared responsibility on the part of all those involved as well as transparency with regard to trends and orientations, costs incurred, and information on practices and their impacts.
Summary of Recommendations

The Commissioner believes that

- The government should maintain Québec's assisted reproduction program but should make significant changes to clarify its objectives and redefine its eligibility criteria, while providing the means to assess whether the program's objectives have been met.
- The program should be re-evaluated after the recommended measures have been implemented, and adjusted based on ensuing results in order to ensure its long-term viability and social acceptability.

To improve program oversight and impact, the Commissioner makes the following recommendations:

Recommendation 1

1.1 Impose limits on access to the program, applicable to all, based on the following factors:

- Eligibility of both partners for the Québec health insurance plan
- Prior voluntary sterilization
- Fertility preservation for social reasons
- Results of psychosocial assessment, if applicable
- Age of the mother (minimum and maximum)
- Number of existing children and number of children conceived through IVF

1.2 Establish consensual guidelines on how to take into account potential success rates (based in part on maternal age) and risk factors for the health of the mother and child (such as genetic factors) as eligibility criteria for the program.

1.3 Use the least invasive techniques possible based on what is medically indicated.
Recommendation 2

2. Promote more equitable access to assisted reproduction services in Québec’s regions by issuing secondary and tertiary care permits based on regional planning and the desired balance between public and private sector services.

Recommendation 3

3.1 Make all program costs public, broken down by category: technical costs, fees, drugs, and infrastructure.

3.2 Periodically review technical costs and adjust amounts earmarked, if necessary, as practices and actual costs evolve.

3.3 Establish the parameters governing the financial contribution to be charged to intended parents, based on income.

Recommendation 4

4.1 Set up, as a matter of urgency, a centralized database permitting longitudinal monitoring of assisted reproduction activities and evaluation of the health impacts on mothers and children.

4.2 Use these data for health surveillance and continuous quality improvement purposes.

Recommendation 5

5.1 Establish a permanent multidisciplinary committee on the development and monitoring of assisted reproduction practices, which will replace the Réseau québécois de procréation assistée, and invite the Collège des médecins du Québec, Institut national de santé publique du Québec, Institut national d’excellence en santé et en services sociaux, and professionals in the field to take part.

5.2 Set up an issue table on assisted reproduction ethics, which could be hosted and supported by a permanent body such as the Commission de l’éthique en science et en technologie.
Recommendation 6

6. Specify in a regulation on assisted reproduction activities that all research in this field, whether conducted in the public or private sector, must be overseen by an independent research ethics committee with the necessary expertise in assisted reproduction.

Recommendation 7

7. Finalize the clarification of roles and responsibilities of all professionals providing assisted reproduction services with respect to all techniques, including ovarian stimulation, artificial insemination, and IVF, in order to minimize the risks associated with assisted reproduction.

Recommendation 8

8.1 Amend the *Regulation respecting clinical activities related to assisted procreation*

- By adding information that must be provided to the people involved, including information on care pathways, accessory fees, and patients’ responsibilities with regard to the assisted reproductive technologies’ success
- By specifying that appropriate counseling must be provided to all parties whenever treatment involves donor gametes, in order to ensure informed consent

8.2 Provide ongoing support for intended parents in clinics

- To enable informed, validated, and up-to-date consent at key points in the process
- To support their decision-making right from the beginning of the IVF process, for example, notably by clarifying the consequences of the choices they face with respect to surplus embryos

Recommendation 9

9. Amend the regulatory framework governing assisted reproduction practices in order to better protect the wellbeing of the future child by specifying the following points:

- Anyone requesting assisted reproduction services must complete a form about their psychosocial history.
• Professionals at assisted reproduction clinics must refer intended parents for a psychosocial evaluation if at any time during the provision of services they have serious cause to suspect potential social or psychological risks to the future child.
• Psychosocial assessments by referral must be performed independently of the clinic, at the expense of the individuals concerned.

Recommendation 10
10.1 Provide for real-time registration of anyone who visits a clinic to obtain services into a centralized database accessible to all clinicians providing assisted reproduction services.

10.2 Record all data on patient trajectories in the database, including number of treatment cycles, referrals for assessment of parental capacity and seriousness of their parenthood plans, and any refusals to provide treatment due to medical or psychosocial reasons, if applicable.

Recommendation 11
11.1 Reimburse the same amount for sperm straws from open-identity donors as for those from anonymous donors.

11.2 Limit the number of sperm straws reimbursed per woman.

Recommendation 12
12.1 Have the issue table on assisted reproduction ethics address two priority themes:

• The disposal of surplus frozen embryos with a view to revising sections 24 and 25 of the Regulation on clinical activities related to assisted procreation within the next year
• The practice of surrogacy in order to thoroughly examine the ethical implications of the recommendations issued by the family law advisory committee

12.2 Adopt a moratorium on the disposal of embryos for which parental consent has not been obtained while sections 24 and 25 of the regulation are being reviewed.

12.3 Launch a societal debate on the social acceptability of surrogacy based on legal, ethical, clinical, and social information.
Appendix I
Mandate received from the Minister of Health and Social Services

Québec

Gouvernement du Québec
Le ministre de la Santé et des Services sociaux
Le ministre responsable des Aînés
Le ministre responsable de la région de l’Estrie

Québec, le 6 février 2013

Monsieur Robert Salois
Commissaire à la santé et au bien-être
1020, route de l’Église, bureau 700
Québec (Québec) G1V 3V9

Monsieur le Commissaire,

Par la présente, j’aimerais obtenir votre avis concernant la pertinence d’offrir certaines activités de procréation assistée.

En effet, le ministère de la Santé et des Services sociaux a été sollicité, au cours des dernières semaines, afin de faire connaître sa position sur diverses situations en lien avec des activités de procréation assistée.

Dans son état actuel, la Loi sur les activités cliniques et de recherche en matière de procréation assistée (chapitre A-5.01) ne limiterait pas l’accès aux services assurés aux seules causes d’infertilité ou de maladie génétique grave.

Les connaissances et les techniques reliées aux activités de procréation assistée étant en évolution constante, des éclaircissements sont nécessaires au sujet de ce qui doit constituer un service assuré dans le cadre du Programme québécois de procréation assistée.

Considérant que plusieurs des demandes qui nous sont adressées soulèvent des questions éthiques et sociales sur des enjeux fondamentaux qui concernent la société québécoise, votre avis sur les activités de procréation assistée, comme prescrit à l’article 9 de la loi précitée, serait grandement apprécié.

Je vous remercie de votre collaboration et je vous prie d’agréer, Monsieur le Commissaire, l’expression de mes sentiments les meilleurs.

Le ministre,

Réjean Hébert

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