Regulatory Failure: The Case of the Private-For-Profit IVF Sector

By Colleen M. Flood and Ryann Atkins

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25 OCTOBER 2011

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Introduction

In December 2010, the Supreme Court of Canada (SCC) ruled that significant portions of the *Assisted Human Reproduction Act* (AHRA) were *ultra vires* federal jurisdiction; specifically, the court struck down provisions that licensed, regulated, and administered the practise of *in vitro fertilisation* (IVF). This decision essentially gave provinces the authority to regulate IVF while allowing a federal ban with criminal law penalties on the buying and selling of sperm, ova, and surrogacy services.[1] The full impact of this decision on the fertility industry remains to be seen, but to understand the implications of this decision for IVF patients, one must explore the context in which IVF services in Canada are provided. In its analysis, the SCC did not mention that the vast majority of IVF services in most of Canada are delivered in private, for-profit clinics and are privately financed. Quebec became the notable exception in August 2010 when the province moved to provide public funding for three cycles of the procedure.[2] Ontario also provides some funding for IVF, but only if both fallopian tubes are blocked by natural causes, just 20% of all IVF cycles performed in 2004 in Ontario.[3]

We argue that unlike publicly financed health care, which attracts considerable regulation and oversight, privately financed health care attracts comparatively light regulation across Canada. Interestingly, in Quebec, the move to publicly finance IVF coincided with a move to regulate the practice further supporting our thesis that public care attracts more regulation than private care, despite the equal or greater need for regulation in the private sector. From a first principles basis, the rationale for regulating the delivery of IVF focuses on safety and quality concerns. These concerns are arguably as significant if not more so in the private sector where there is often a profit motive affecting operational decision-making. We discuss the literature both for and against the contention that there are greater concerns around quality and safety in for-profit delivery than in public or not-for-profit delivery. Furthermore, because of the commercial nature of IVF delivery, patients also face potential conflicts of interests on the part

[1] *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at para 294, 327 DLR (4d) 257; *Assisted Human Reproduction Act*, SC 2004, c 2.
[2] *Regulation respecting the application of the Health Insurance Act*, RRQ 2011, c A-29, r 5, s 34.4; "FAQ" online: McGill Reproductive Centre <www.mcgillivf.com> (accessed 19 May 2011).
[3] "In Vitro Fertlization and Multiple Pregnancies: an evidence-based analysis", online: (2006) 6(18) Ontario Health Technology Assessment Series 2006 at 21 < www.health.gov.on.ca/english/providers/.../rev_ivf_101906.pdf> at 21.

of providers that may affect the amount and quality of information they receive on their real chances of success, and patients may not be sufficiently informed of this risk.

Unfortunately, federal regulation in this area, which has now largely been overturned by the SCC, and the laws promulgated in Quebec, speak more to restricting reproductive freedom than to improving the safety and quality of IVF services or alleviating concerns about informational failures and conflicts of interest. We suggest what regulation is necessary vis-à-vis the delivery of IVF services by analyzing the regulatory governance of IVF in Ontario and Quebec and assessing whether this is sufficient to address the above concerns. In our analysis we acknowledge the fact that private financing can make access to such services challenging for many, and thus our regulatory prescriptions seek to be as efficient as possible, enhancing the safety and quality of IVF services whilst not unduly increasing the potential cost of services. We are particularly concerned with the safety, quality, and cost of IVF health services and as such, this paper will not address the law and ethics of donor and birth parent privacy. This paper is not advocating for or against public funding for IVF; rather, it simply asks what regulations are necessary to protect patients in light of the context of private delivery and/or financing.

The Context of IVF Delivery and Financing in Canada

The SCC decision on the constitutionality of the AHRA did not explore or even mention the context of IVF delivery and financing in Canada. This backdrop is crucial to understanding the regulatory needs of the fertility industry and therefore the rationale behind the promulgated laws. We shall explore this context here.

There are currently just over thirty fertility clinics in Canada that perform IVF.[4] Most IVF services are delivered by for-profit clinics. For example, in Ontario, there are twelve private IVF clinics that perform IVF. In contrast, five public hospitals (i.e. run on a not-for-profit basis) are classified as IVF hospitals and only three currently run IVF clinics (which are not necessarily run on a not-for-profit basis).[5] Quebec seems to be an outlier in this regard. There are five IVF

[4] Note: There may be many more clinics that offer IVF, however these clinics do not perform the procedure themselves but rather are affiliated with one of the thirty-or-so clinics that do (Joanne Gunby, "Assisted reproductive technologies (ART) in Canada: 2008 results from the Canadian ART Register", online: Canadian Fertility and Andrology Society <www.cfas.ca/index.php?option=com_content&view=article&id=1076&Itemid=668> (Accessed 29 May 2011)).

[5] Joanne Gunby, "Assisted reproductive technologies (ART) in Canada: 2008 results from the Canadian ART Register", online: Canadian Fertility and Andrology Society <www.cfas.ca/index.php?option=com_content&view=article&id=1076&Itemid=668> (Accessed 29 May 2011);

clinics in the province, three of which are run on a not-for-profit basis through public hospitals. The private clinics, however, have multiple branches, so there is still a strong presence of the private sector in IVF delivery.[6] The government of Quebec anticipates that within a few years, all delivery within the province will be provided through public (i.e. not-for-profit) institutions.[7]

The majority of IVF is also privately financed. Most Canadian provinces do not offer any public funding through provincial health insurance plans for these procedures. Some provinces, like Manitoba, offer couples an income tax refund for a portion of the costs of infertility treatment, but the couples must still finance the treatment out of their own private funds.[8] Usually, private financing means that a couple will have to cover the cost of treatment out of their own pocket since private health insurance companies in Canada generally do not cover IVF.[9] Some private insurance plans will cover the cost of fertility drugs, but a single cycle of IVF may still cost over $10,000.[10]

There are two exceptions to private financing. In Ontario, IVF is publicly insured through the Ontario Health Insurance Plan (OHIP) when the indicator of infertility is a bilateral tube blockage (i.e. both fallopian tubes in the female are blocked) and only if this condition has not been caused by a voluntary sterility procedure.[11] This is a very narrow exception,

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"Classification of Hospitals" *Ministry of Health and Long Term Care Ontario*, online: Ministry of Health and Long Term Care Ontario < http://www.health.gov.on.ca/english/public/contact/hosp/group_q.html> (Accessed 12 May 2011); "Fertility Specialist Resourcs" *IVF.ca*, online: < http://www.ivf.ca/clinicprov.php> (Accessed 12 May 2011); Note: In Canada, "public hospital" refers to a hospital that operates on a not-for-profit basis, not a hospital that belongs necessarily to the public sector (see: Raisa Deber, "Delivering Health Care Services: Public, Not-for-Profit, or Private?" *Commission on the Future of Health Care in Canada: Discussion Paper No.17*, online: <http://www.teamgrant.ca/M-THAC Greatest Hits/ Bonus Tracks/Delivering Health Care Services.pdf> (Accessed 29 August 2011)).

[6] Joanne Gunby, "Assisted reproductive technologies (ART) in Canada: 2008 results from the Canadian ART Register", online: Canadian Fertility and Andrology Society <www.cfas.ca/index.php?option=com_content&view=article&id=1076&Itemid=668> (Accessed 29 May 2011).

[7] "Dès le 5 Août 2010, les couples infertiles du Québec pourront bénéficier de la couverture des traitements de procréation assistée pour réaliser leur rêve d'voir un enfant" CNW Telbec (13 July, 2010), online: Quebec Portal <http://communiques.gouv.qc.ca/gouvqc/communiques/GPQF/Juillet2010/13/c3987.html?slang=en> (Accessed 20 May 2011).

[8] Robin Hilborn, "Provincial help for the infertile in Canada: free IVF in Quebec, tax help in Manitoba, Ontario balks" *Fertility Helper* (16 September 2010) Fertility Helper < http://www.familyhelper.net/iy/news/100917quebecivf.html> (Accessed 16 May 2011).

[9] [only info through a fertility forum, sunlife/Manulife etc did not return emails]

[10] [only info through a fertility forum, sunlife/Manulife etc did not return emails]

[11] "In Vitro Fertlization and Multiple Pregnancies: an evidence-based analysis", online: (2006) 6(18) Ontario Health Technology Assessment Series 2006 at 21 < www.health.gov.on.ca/english/providers/.../rev_ivf_101906.pdf> at 21.

constituting approximately 20% of all IVF procedures in 2004.[12] A provincial study moreover indicated that the actual demand for IVF is not reflected in the number of cycles performed, as demand would increase if the treatment were more affordable. The 2006 report predicted that the number of cycles in Ontario would increase three-fold if every indicator of infertility received public financing.[13] It is likely therefore, that bilateral tube blockage describes far fewer than 20% of all infertile couples in Ontario. Every other indicator of infertility, including all forms of male infertility, is uninsured and must be covered privately.

The exception to private financing is the province of Quebec. As of August 2010, the provincial government in Quebec funds up to three stimulated cycles of IVF or up to six natural or modified natural cycles of IVF, provided that only one embryo is transferred at a time (to a maximum of two or three embryos depending on the patient's age). To access funding, a patient must be a Quebec resident who qualifies for coverage by the provincial health insurance plan, RAMQ.[14] Private financing of IVF services is actually forbidden in Quebec unless the patient has unsuccessfully undergone the insured IVF services or the patient does not qualify for RAMQ coverage because of age or residency status.[15]

Regulatory Challenges Associated with IVF and Privatized Health Care

Invasive medical procedures generally entail certain risks, and IVF is no exception. The IVF process itself carries risks for both the mother and the potential future child. For example, if more than one embryo is transferred at a time, there is a risk that multiple pregnancies will occur, a condition that could cause anaemia, toxaemia, and kidney trouble for the mother, in addition to a more difficult delivery and longer recovery time.[16] There is a higher risk of premature birth

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[12] "In Vitro Fertlization and Multiple Pregnancies: an evidence-based analysis", online: (2006) 6(18) Ontario Health Technology Assessment Series 2006 at 21 < www.health.gov.on.ca/english/providers/.../rev_ivf_101906.pdf> at 21.

[13] "In Vitro Fertlization and Multiple Pregnancies: an evidence-based analysis", online: (2006) 6(18) Ontario Health Technology Assessment Series 2006 at 21 < www.health.gov.on.ca/english/providers/.../rev_ivf_101906.pdf> at 33.

[14] *Regulation respecting the application of the Health Insurance Act*, RRQ 2011, c A-29, r 5, s 34.4; "FAQ" online: McGill Reproductive Centre <www.mcgillivf.com> (accessed 19 May 2011).

[15] "Fees" online: McGill Reproductive Centre <www.mcgillivf.com> (accessed 19 May 2011).

[16] Paula Corabian and David Hailey, "The Efficacy and Adverse Effects of *In Vitro* Fertilization and Embryo Transfer" (1999) 15(1) Int'l J of Technology Assessment in Health Care at 78; Ivica Tadin, et al., "Fetal Reduction in Multifetal Pregnancy: Ethical Dilemmas" (20020 43(2) Yonsei Medical Journal at 252.

and consequently low birth weight in children born in multiples (i.e. twins or higher).[17] There is also a risk of infection associated with the extraction of ova as part of the IVF process, which in turn can cause or exacerbate existing fertility problems. Studies have found that this occurs in approximately 0.6-1.3% of cases.[18] Moreover, the fertility drugs used as part of IVF treatment carries the risk of ovarian hyper-stimulation syndrome for the mother, which in very rare cases can be life-threatening.[19]

These are risks associated with IVF that exist regardless of where the procedure is performed and how it is financed; however, private clinics may participate in activities that exacerbate the health risks of IVF in order to improve their bottom lines. Important evidence in this regard is Devereaux's meta-analysis study, which synthesized the findings of 15 smaller studies (reviewing a total of 26,000 hospitals and 38 million patients) comparing the adjusted mortality rates of public and private clinics between 1982 and 1995.[20] Adjusting for factors such as the facility's teaching status and the severity of illnesses treated, the analysis found that private for-profit clinics are associated with an increased risk of death (relative risk [RR] 1.020).[21] Information included in the study suggests that not-for-profit facilities serve populations with greater disease severity. Devereaux noted that for this reason, the disparity in mortality rates may even be an underestimate.[22]

Devereaux explains that investors in for-profit facilities expect a 10%-15% return and the system generally rewards administrators who achieve or exceed this profit margin. Combined with other cost pressures like taxes and reimbursement packages for administrators, there is a

[17] Simone E. Buitendijk, "Children after In Vitro Fertilization" (1999) 15(1) Int'l J of Technology Assessment in Health Care at 53; Ivica Tadin, et al., "Fetal Reduction in Multifetal Pregnancy: Ethical Dilemmas" (20020 43(2) Yonsei Medical Journal at 252.
[18] Emma Sowerby & John Parsons, "IVF: how can we reduce the risks of infection?" (2006) 8 The Obstetrician & Gynaecologist at 160.
[19] Note: the precise mortality rate of ovarian hyperstimulation syndrome is unknown and difficult to quantify; however, a 2005 report suggests that the figure is probably approximately 1/450,000 in the UK (Adam Balen, "Ovarian hyper stimulation syndrome: A short report for the HFEA", online: HFEA <http://www.hfea.gov.uk/docs/OHSS_UPDATED_Report_from_Adam_Balen_2008.pdf>).
[20] P.J. Devereaux et al., "A systematic review and meta-analysis of studies comparing mortality rates of private for-profit and private not-for-profit hospitals" (2002) 166(11) CMAJ at 1400, 1402.
[21] P.J. Devereaux et al., "A systematic review and meta-analysis of studies comparing mortality rates of private for-profit and private not-for-profit hospitals" (2002) 166(11) CMAJ at 1400.
[22] P.J. Devereaux et al., "A systematic review and meta-analysis of studies comparing mortality rates of private for-profit and private not-for-profit hospitals" (2002) 166(11) CMAJ at 1404.

significant motivation to cut costs at for-profit clinics.[23] The study avoided, where possible, adjustment for variables that are under the control of hospital administrators that may be influenced by profit considerations and which may affect mortality, including staffing levels (e.g. nurses per bed, pharmacists per bed).[24] Two studies that did adjust for staffing levels (in particular, for registered nurses as a proportion of all nurses and the proportion of board-certified specialists among all physicians) found that the higher risk of mortality associated with for-profit ownership decreased, suggesting that that employing less-highly skilled personnel per risk-adjusted bed is at least a contributing factor to the higher mortality rate.[25]

A second systematic review and meta-analysis conducted by Devereaux, this time comparing the mortality rates of private for-profit and private not-for-profit dialysis facilities in the United States similarly associated a higher mortality rate with for-profit clinics (RR 1.08).[26] The study combined the results of 8 observational studies with a median of 1342 facilities per study, amounting to 500,000 patient-years of data. Of these studies, 6 studies showed significant increased mortality with for-profit dialysis facilities and 1 showed non-significant increased mortality.[27] This study is significant because it takes place entirely within the realm of publicly funded medicine as the US government has funded dialysis under Medicare since 1973.[28] Moreover, the implications of the findings of this study are huge. Approximately 20-25% of in-center hemodialysis patients in the United States die each year. Based on the 8% relative risk of death and the fact that 75% of patients attend for-profit facilities for this treatment, the authors estimate that there are 2500 excessive premature deaths annually in the US in for-profit dialysis centers.[29]

[23] P.J. Devereaux et al., "A systematic review and meta-analysis of studies comparing mortality rates of private for-profit and private not-for-profit hospitals" (2002) 166(11) CMAJ at 1404.
[24] P.J. Devereaux et al., "A systematic review and meta-analysis of studies comparing mortality rates of private for-profit and private not-for-profit hospitals" (2002) 166(11) CMAJ at 1401.
[25] P.J. Devereaux et al., "A systematic review and meta-analysis of studies comparing mortality rates of private for-profit and private not-for-profit hospitals" (2002) 166(11) CMAJ at 1402, 1405.
[26] P.J. Devereaux et al., "Comparison of Mortality Between Private For-Profit and Private Not-for-Profit Hemodialysis Centers: A Systematic Review and Meta-analysis" (2002) 288(19) JAMA at 2449.
[27] P.J. Devereaux et al., "Comparison of Mortality Between Private For-Profit and Private Not-for-Profit Hemodialysis Centers: A Systematic Review and Meta-analysis" (2002) 288(19) JAMA at 2449, 2452.
[28] P.J. Devereaux et al., "Comparison of Mortality Between Private For-Profit and Private Not-for-Profit Hemodialysis Centers: A Systematic Review and Meta-analysis" (2002) 288(19) JAMA at 2450.
[29] P.J. Devereaux et al., "Comparison of Mortality Between Private For-Profit and Private Not-for-Profit Hemodialysis Centers: A Systematic Review and Meta-analysis" (2002) 288(19) JAMA at 2449, 2452.

Similarly to the previous study, Devereaux notes that the issue is at least party one of cost-cutting through inadequate staffing. Studies show that for-profit dialysis centers employ fewer personnel per dialysis run and less-highly skilled personnel in general.[30] The study also found that for-profit facilities use shorter durations of dialysis treatments, which are associated with higher mortality.[31]

[insert research from Hillmer, Eggleston which suggests the same thing – Jill Horowitze on the benefits of not-for-profit over for-profit]. On the other hand, [set out any studies that say not a prob/reach conclusion that it is possible to ameliorate through regulation—]

The commercial context of privately financed treatments delivered by for-profit institutions also raises special concerns for patients. It is widely accepted that there is an information asymmetry existing between the physician and the patient, irrespective of where treatment is procured. In other words, the physician will have information about risks, quality, safety, etc. that the patient will likely not know unless the information is actively disclosed to him or her. Patients must often rely on the physician for the information necessary to make a decision since they lack the requisite medical expertise themselves. This raises the issues of consumer protection and informed consent. Arguably, these problems are exacerbated in for-profit settings. Combined with the profit motive of many private clinics, this is a real conflict of interest that could lead physicians to prescribe unnecessary treatments, to present the risks associated with IVF in a certain light, to neglect to inform a patient about non-medical or less invasive alternatives, or to otherwise present information to a patient in a self-interested way.

Applied to the IVF case, there is an incentive to transfer multiple embryos at one time so as to increase the chance that one will implant and result in pregnancy. This would not only increase their pregnancy rate, but would also be an attractive option for couples without the financial resources to undergo multiple cycles of expensive IVF treatment. Unfortunately, this increases the risk of multiple pregnancies in some cases, which as we have noted above, poses health risks to both mother and child. If private clinics want the additional business that these couples could bring, this may affect the way in which these risks are presented to the patients. Another example involves the way in which a clinic advertises its services. A clinic may only

[30] P.J. Devereaux et al., "Comparison of Mortality Between Private For-Profit and Private Not-for-Profit Hemodialysis Centers: A Systematic Review and Meta-analysis" (2002) 288(19) JAMA at 2456.
[31] P.J. Devereaux et al., "Comparison of Mortality Between Private For-Profit and Private Not-for-Profit Hemodialysis Centers: A Systematic Review and Meta-analysis" (2002) 288(19) JAMA at 2456.

present the statistics that reflect favourably on its practice. A clinic's fertilization, pregnancy, and live birth rates, for example, may paint very different pictures of the clinic's success, especially when factors that affect the IVF process, like maternal age and health and the number of embryos transferred, are omitted. Since patients rely heavily on their physicians to provide all of the relevant information that they will need to make a decision, this has huge implications for the quality of the patient's consent. A third problem which stems from this potential conflict of interest is the idea of self-referral. Choudhry et al note that where physicians work part-time in both the public and private sectors there is a possibility that they may refer public patients to clinics where they have an ownership or other economic interest.[32] Similarly, many IVF clinics offer their own diagnostic services. They have the ability to diagnose infertility, prescribe treatment, and then sell that treatment to the patient.[33] This creates a risk that physicians may diagnose infertility and recommend IVF treatment as well as costly add-ons like intracytoplasmic sperm injection (ICSI) in order to make a profit, even when it is not necessary or in the patient's best interest to do so.

The Inadequacy of Non-IVF Specific Regulations

In 2004, the federal Assisted Human Reproduction Act divided activities associated with the practice and study of assisted human reproduction into those that are prohibited and those that ought to be controlled. The SCC was asked by the province of Quebec to decide whether certain provisions of the AHRA that dealt with the so-called 'controlled activities', like IVF, were ultra vires federal jurisdiction. The Attorney General of Quebec targeted these provisions arguing that they constituted an attempt to regulate medical practice, an area that has historically fallen within provincial jurisdiction under sections 92(13) and 92(16) of the Constitution.[34] The Attorney General of Canada defended these provisions as a valid use of the federal criminal law power under section 91(27) of the Constitution.[35] In a 4-4-1 split decision released in December 2010, the court allowed the appeal in part, striking down the provisions that empowered the federal Assisted Human Reproductive Agency to license and regulate the practice of IVF.

[32] Sujit Choudhry, et. al., "Unregulated private markets for health care in Canada? Rules of professional misconduct, physician kickbakcs and physician self-referral" (2004) 170(7) CMAJ at 1115.
[33] See for example Astra Fertility Group <http://www.astrafertility.com/diagnostic.html>.
[34] *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at para 7, 327 DLR (4d) 257.
[35] *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at para 6, 327 DLR (4d) 257

Relying substantially on the recommendations of the Baird Commission that prompted the legislation, LeBel and Deschamps found the pith and substance of these provisions to be regulatory.[36] Moreover, they argue that for a regulatory scheme to be valid criminal law it must target either a harm or a moral evil, otherwise the criminal law power becomes too broad.[37] In the case of the impugned provisions, no moral evil or harm was identified; in fact, the Baird Commission that had been the impetus for federal legislation considered the "controlled" activities beneficial.[38] It is important to note that the Act's "prohibited" activities set out in sections 5 to 7 were not challenged and therefore remain in force. These include human cloning, screening for sex for non-medical purposes, permanently altering the genome of an embryo so that the alterations would be passed down to descendants, creating chimeras or animal hybrids, paying surrogates or intermediaries to a surrogacy contract, using a surrogate mother under the age of 21, and the sale of gamete material.[39] The provisions on prohibited activities were not challenged because the province of Quebec conceded that they were a valid exercise of the federal criminal law power against harmful, morally abhorrent activities. While the SCC was not asked to rule on these provisions, all three judgments seem to support this conclusion.[40] The sections of the AHRA thatwere explicitly upheld by the majority of the court were found to be sufficiently related to the criminal law purpose behind the uncontested provisions to fall under the ancillary powers doctrine.[41]

The court essentially ruled that the regulation of the delivery of IVF services primarily lies in the hands of the provinces. To date, the great majority of Canadian provinces have yet to take up this challenge. The first child conceived through in vitro fertilization was born in 1978 and the first Canadian child in 1983.[42] It took twenty-one years for the federal government to attempt to regulate the practice through the AHRA. In 2010, Quebec became the first province to directly regulate IVF, twenty-seven years after the technology's appearance in Canada. In terms of regulating IVF, most provinces in Canada resemble Ontario. There is no specific

[36] *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at para 227, 327 DLR (4d) 257.
[37] *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at paras 236, 238, 243, 327 DLR (4d) 257.
[38] *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at para 250, 327 DLR (4d) 257.
[39] *Assisted Human Reproduction Act*, SC 2004, c 2 ss 5-7.
[40] See *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at paras 10, 166, 327 DLR (4d) 257.
[41] *Reference Re Assisted Human Reproduction Act*, [2010] SCC 61 at paras 141, 147, 290, 292,293, 327 DLR (4d) 257.
[42] "First test-tube babies born in Canada turn 25" *Canadian Press* (24 March 2007), online: CTV News < http://www.ctv.ca/CTVNews/World/20070324/test_tube_070324/> (Accessed 5 June 2011).

legislation that addresses IVF; instead the practice of IVF is affected by broader legislation pertaining to health care and health care professionals generally. Quebec has similar pieces of legislation that pre-date and supplement the more specific regulations that were recently enacted. As we discuss, these lighter forms of regulation do not sufficiently address or attend to the safety, quality, and consumer concerns arising from the delivery of IVF services in the context of private, for-profit clinics.

Safety and Quality of Care

In Ontario, concerns about the safety and quality of IVF procedures in private for-profit clinics are governed by the regulatory regime that applies to health care and health care professionals in general. The *Regulated Health Professions Act* (RHPA) empowers the Ontario College of Physicians and Surgeons (CPSO) Discipline Committee to act in cases of professional misconduct.[43] In addition, the *Medicine Act*, Regulation 114/94 established a Quality Assurance Committee, also administered through the CPSO.[44] Quality of care and safety in private Ontario clinics are thus subject to professional self-regulation. Self-regulation has a number of drawbacks. First, it tends not to be proactive. In terms of prevention, there is no regular inspection mechanism in place to uncover breaches of the standards of care. Enforcement generally requires patient complaints to bring concerns to light, which is problematic because patients may not necessarily be able to detect failings in quality and safety. Moreover, patients may not report their complaints if they are concerned about jeopardizing the physician-patient relationship – a particular problem in specialty IVF clinics that may be a monopoly in certain areas. Second, under a system of self-regulation, only the most egregious breaches of care tend to attract sanctions. The emphasis is placed rather on retraining than on discipline. This is arguably a weaker deterrent.

Likewise, in Quebec, the *Code of ethics of physicians* provides general provisions regarding the quality and safety of services delivered, and the *Professional Code* mandates the creation of an inspection committee to supervise the professional practice.[45] The committee may recommend refresher training and suspend a member's right to practice until training is

[43] *Regulated Health Professions Act, 1991*, SO 1991, c 18 s 10.
[44] *Medicine Act General Regulations*, O Reg 114/94 s 27.
[45] *Code of ethics of physicians*, RRQ 2008, c M-9, r 4.1; *Professional Code*, RSQ 2010, c C-26, s 109.

complete.[46] The emphasis, again, is on retraining and not on sanctions. For these reasons, the non-IVF specific regulation across Canada is insufficient in our view to protect against the real safety and quality challenges inherent in the delivery of invasive IVF procedures, exacerbated in the context of privately-financed and privately-delivered care.

(NEED TO DISCUSS THE REGULATION OF FACILITIES)

Conflicts of Interest and Informed Consent

In Ontario, the *Health Care Consent Act* (HCCA)[47] and the common law apply to all health care settings, including private, for-profit clinics. The HCCA requires a patient to be informed of the nature of the treatment, the expected benefits, the material risks, the material side effects, alternative courses of action, and the consequences of foregoing the treatment.[48] The common law on informed consent requires a patient to be informed of the material risks and alternative courses of treatment. The physician must also ensure that a patient understand the risks.[49] The fact that these laws exist does not mean that they are effectively enforced. The *HCCA* is enforced through the *Medical Act Regulation 856/93* which allows physicians to be sanctioned with a suspension or revocation of their license, conditions placed on their license, or a substantial fine.[50] **[Still searching for information on how is this monitored**]. The common law on informed consent can be enforced through the civil court system but litigation is a weak deterrent as even if a patient is able to establish that physician did not properly appraise her of the risks, she then must establish causation on the basis that a reasonable person in her shoes would not have undertaken the treatment given the risks disclosed**. {citation for low levels of success in informed consent litigation]** Unfortunately, evidentiary and financial hurdles make pursuing a patient's rights in court difficult. Given the information asymmetry characteristic of the health care industry, a patient may not be aware of his or her rights or whether medical negligence has occurred. Moreover, IVF is a very costly, as is pursuing a lawsuit. Patients may be unable to afford expensive legal claims in addition to their medical expenses. Similar problems arise out of the general regulations of informed consent found in Quebec *civil code* and

[46] *Professional Code*, RSQ 2010, c C-26, s 113.
[47] *Health Care Consent Act*, SO 1996, c2 (Sch A).
[48] *Health Care Consent Act*, SO 1996, c2 (Sch A). ss 11(1)(2)(3).
[49] "Canadian Health Facilities Law Guide," (Toronto: CCH Canadian Limited, 2003) at 1510.
[50] *Medicine Act Professional Misconduct Regulations*, O Reg 856/93, s1(1)9.

professional code.[51] It should be noted that the weaknesses that we found in the regulations designed to protect a patient's right to informed consent exist in both the public and private sectors of health care. However, in the context of private, for-profit clinics, informed consent arguably take on a greater importance given the potential for conflicts of interest that may arise between the physician and patient. Therefore, we find that there is a need for stronger regulations for commercialized procedures like IVF, to ensure that patients are making decisions based on the fullest information possible.

Conflicts of Interest and Consumer Protection

Besides the amount and quality of information disclosed to the patient about the procedure, the potential conflict of interest inherent in the private, for-profit setting may affect how a clinic advertises its services. This raises the issue of consumer protection: the advertisement of services offered by private, for-profit clinics must be regulated in a way that protects the interests of the patient-consumer. In Ontario, *Regulation 114/94*[52] prohibits false, misleading, or exaggerated claims in advertising; however, this provision is largely unused. Other activities that may result from a conflict of interest in the delivery of health care services are regulated under the *Health Professionals Procedural Code*, which states that medical duties must always supersede any corporate or proprietary duties[53], and the *Medical Act Regulation 114/94*, which states that it is a conflict of interest for a member to order a diagnostic or therapeutic service to be performed by a facility in which the member or a member of his or her family has a proprietary interest unless that conflict is disclosed to the patient.[54] It should be noted that this is not an absolute ban on acting in the face of a potential conflict but rather a requirement that such conflicts be disclosed. Similarly, in Quebec, the *Code of ethics of physicians* requires that a physician avoid any situation that would give rise to a conflict of interest where his integrity and loyalty toward the patient might be affected.[55] This is, again, a qualified statement. The physician is not required to avoid any conflict of interest, but only those where his integrity and loyalty might be affected. More specifically, the code states that a physician must refrain from seeking undue profit from the prescription of medications,

[51] *Code of ethics of physicians*, RRQ 2008, c M-9, r 4.1, s 28-29; *Act respecting health services and social services*, RSQ 2011, c S-4.2, ss 8, 9; *Civil Code of Quebec*, RSQ 1991, c 64, 11.
[52] *Medicine Act General Regulations*, O Reg 114/94.
[53] *Regulated Health Professions Act*, SO 1991, c 18 (Sch II), ss 85.11(1), 85.12.
[54] *Medicine Act General Regulations*, O Reg 114/94, s 17(1).
[55] *Code of ethics of physicians*, RRQ 2008, c M-9, r 4.1, s 63.

examinations, or treatments.[56] There is not precise explanation given for this provision. It is not clear that this would even touch the issue of self-referral. In fact, the code states, as in Ontario, that a physician must inform the patient of the fact that he or she has interests in the enterprise providing the services that he prescribes, which suggests that self-referral is a permitted practice.[57] Compounding the weakness of these regulations is inadequate enforcement. In Ontario, it is up to the College of Physicians and Surgeons to enforce these regulations. As we argued above, relying on self-regulation alone is inadequate given the information asymmetry inherent to the health care system and the desire for patients to maintain care relationships with their physician, resulting in under-reporting of safety and quality issues. The non-IVF specific regulations on consumer protection and conflicts of interest therefore neglect to address or amend the real risks that patients face in the private, for-profit sector.

The Inadequacy of IVF-specific Regulations

Even when a province has undertaken to regulate IVF specifically, the resulting 'targeted' legislation, although a significant improvement, still insufficiently protects the vulnerable individuals seeking IVF treatment and instead focuses more on limiting reproductive autonomy. In August 2010, the provincial government of Quebec enacted the *Act respecting clinical and research activities relating to assisted procreation*[58], and the *Regulation respecting clinical activities related to assisted procreation*.[59] To date, it is the only province to do so. Unfortunately, these regulations do not actually fill-in the gaps left by pre-existing provincial laws that address IVF indirectly.

Safety and Quality of Care

In terms of quality and safety, the new Quebec regulations take a few different measures to mitigate the risks associated with the practice of IVF. First, like the AHRA did before, it sets out a licensing scheme for all clinics that offer IVF services. Licenses are issued by the Minister of Health and Social Services for three-year terms and are subject to renewal.[60] Moreover, licenses may be conditional, suspended, revoked, or refused if it is in the public interest or if the

[56] *Code of ethics of physicians*, RRQ 2008, c M-9, r 4.1, s 73.
[57] *Code of ethics of physicians*, RRQ 2008, c M-9, r 4.1, s 77.
[58] *An Act respecting clinical and research activities relating to assisted procreation*, RSQ 2010, c A-5.01.
[59] *Regulation respecting clinical activities related to assisted procreation*, RRQ 2010, c A-5.01, r 1.
[60] *An Act respecting clinical and research activities relating to assisted procreation*, RSQ 2010, c A-5.01, s 20.

facility's practices fall below the standards of quality, safety, or ethics, in the opinion of the Ordre professionnel des médecins du Quebec (i.e. the College of Physicians).[61] To be licensed, IVF facilities must be owned and operated by physicians in good standing (in the case of a corporation, 50% of shares and operational control must be rest with physicians), and directed by a physician with a specialist's certificate in obstetrics-gynaecology. **[Still checking literature to see if physician-owned companies act differently].**[62] There is also a requirement that the physician who operates the clinic have entered into a service agreement with a hospital so that a patient may be directed there if complications arise.[63] Conducting IVF procedures in a facility that does not have a license or otherwise does not meet the scheme's requirements constitutes an offence that carries with it a fine of $2,000-30,000 for natural persons and $6,000-90,000 for legal persons (i.e. corporations). The act contains similar penalties for its other regulations.[64]

The licensing requirement for facilities who wish to perform IVF does provide a mechanism through which the province can set standards and monitor clinics; however, the renewal process only occurs once every three years and, although the act gives the province the power to appoint inspectors, there does not seem to be a regular inspection mechanism in place to enforce this law and the offenses it creates. This suggests that there must still be a patient complaint before any problems are addressed. Moreover, placing conditions or suspensions on licenses is at the discretion of the College of Physicians. In other words, even though a government ministry issues the licenses, the issue of sanctions is still a matter of self-regulation.

Even if these provisions were properly enforced, there are problems with the provisions themselves that could limit their effectiveness in terms of quality and safety. **[Insert research on whether licensing regimes actually improve quality and safety]**. In addition, at first glance the requirement that a clinic be owned and operated by doctors may be an attempt to ensure that the owners/operators are all subject to the code of ethics that all physicians must abide. The purpose of this input measure could also be an attempt to guarantee a certain level of care so that patients can trust that qualified individuals are running a clinic without having to do independent research. On the other hand, it does not follow that every physician working in the clinic is experienced in the often complicated procedures associated with IVF simply because the

[61] *An Act respecting clinical and research activities relating to assisted procreation*, RSQ 2010, c A-5.01, ss 19, 32.
[62] *An Act respecting clinical and research activities relating to assisted procreation*, RSQ 2010, c A-5.01, ss 4-5.
[63] *Regulation respecting clinical activities related to assisted procreation*, RRQ 2010, c A-5.01, r 1, s 2.
[64] *An Act respecting clinical and research activities relating to assisted procreation*, RSQ 2010, c A-5.01, ss 6, 15, 36.

clinic is owned and operated by doctors. Presumably, a collective of orthopaedic surgeons could own an IVF clinic and still hold a license. Moreover, appropriate staffing means sufficient numbers of support staff and appropriately trained individuals at all levels. This provision does not guarantee, for example, the number and training of nurses and assistants.

In terms of safety and quality, the main plank of legal protection is that the procedure is now offered with public financing. Individuals seeking IVF treatment are, for the most part, prevented from accessing private services and must comply with restrictions the IVF treatment, such as the restriction on multiple embryo implants, in order to receive government funds.[65] This will naturally diminish the chances of multiple births and the attendant health and safety risks for mother and child. However, these broad-strokes measures to which financing is tied comes with additional costs to certain patients. We will discuss the drawbacks of this method of regulating later in this paper.

Conflicts of Interest and Informed Consent

The new scheme shows promise in providing rules on what information must be provided to an IVF patient in order for consent to be truly informed or "enlightened". In particular, the patient must be told of the risk of multiple pregnancies and must be told the specific procedures used and their rates of success.[66] However, even this more IVF-tailored informed consent requirement is inadequate to fully correct for the information asymmetry and to protect patients. The success rates across particular IVF clinics vary widely.[67] The law does not specify whether the success rate reported must be the personal rate of the physician or clinic or whether a national average will suffice. Nor does it define what "success rate" actually means. It could refer to the fertilization rate, the implantation rate, the clinical pregnancy rate, the birth rate, or the live birth rate. Only one of those rates indicates that the patient achieved her goal. Ideally, informed consent would mean that the patient is given all of this information. Moreover, as a number of factors may have an impact on the efficacy of IVF treatment (including, but not limited to patient age, health, indicator of infertility (different forms of infertility carry very different prognoses,

[65] *Regulation respecting clinical activities related to assisted procreation*, RRQ 2010, c A-5.01, r 1, s 17.
[66] *Regulation respecting clinical activities related to assisted procreation*, RRQ 2010, c A-5.01, r 1, s 20(1)(2).
[67] Note: For example, according to the most recent information on their respective websites, the clinical pregnancy rate for women under 35 using fresh embryo transfers is 51% at CReATe <http://www.createivf.com/ivf/index.htm>, 60.1% at ReproMed <http://www.repromed.ca/fertility_success.html>, and 54.6% at Astra Fertility <http://www.astrafertility.com/strength_ratios.html> (Accessed 26 May 2011).

not all of which can be treated with IVF), and number of embryos transferred), any success rate that is reported should be similarly broken-down. This may be an even more important protection when patients are paying privately for treatment, but even when IVF is publicly funded, given the stress and risks associated with IVF treatment, patients are entitled to know the true rates of success of particular clinics.

Conflicts of Interest and Consumer Protection

Competition between private clinics for patient-customers may encourage the advertisement of only a clinic's best "success rate", whatever that may be. This law noted above clearly does not correct that issue. Besides the incomplete disclosure requirement, the new legislation on IVF does not offer any additional consumer protection provisions and it does not provide any regulations to prevent any practices that result from potential conflicts of interest in the private sphere. It could be that because Quebec anticipates that the delivery of IVF will be wholly shifted to the public sector in a matter of years the government did not regard this issue as a pertinent problem. Unfortunately, this gap leaves current consumers of IVF services vulnerable. Public financing of IVF does not remove the profit motive of private, for-profit clinics. The meta-analytical study by Devereaux illustrates this point, as the study was conducted in a situation of full public funding (US Medicare) and private, for-profit delivery.[68] The person or entity that pays for medical services does not alter the behaviour of the person or entity who delivers the medical services. For this reason, the current laws specific to the practice of IVF are severely lacking.

The Impact of Regulations on Reproductive Freedom

The IVF regulations in place both nationally and in the province of Quebec succeed in restricting reproductive freedom, even as they fail to adequately protect IVF patients from the risks inherent to the procedure and the industry. Public financing for IVF in Quebec does improve access to IVF for many by alleviating the financial burden of treatment for the vast majority of the infertile population. This can be seen as increasing the reproductive freedom of couples. However, this access is denied to certain groups, and patient autonomy with regards to treatment is at times severely limited by the restrictions tied to public financing. There are three

[68] P.J. Devereaux et al., "Comparison of Mortality Between Private For-Profit and Private Not-for-Profit Hemodialysis Centers: A Systematic Review and Meta-analysis" (2002) 288(19) JAMA at 2450, 2452.

notable regulations that restrict reproductive freedom in Canada: the national ban on commercial surrogacy and the sale of gamete material (sperm and ova), the law in Quebec that states that only one embryo is permitted to be transferred into a woman in any particular cycle, and the law in Quebec which forbids an embryo from being transferred into a woman who is "no longer of childbearing age".[69]

There are several sections of the AHRA that remain intact following the SCC reference. Notably, the province of Quebec did not challenge the prohibitions on activities like human cloning and, more importantly for our purposes, the 'commercialization of reproduction'. The SCC upheld the provision related to the ban on commercial surrogacy that empowers the Assisted Human Reproduction Agency to regulate the compensation of a surrogate's allowable expenses; however, this provision has yet to come into force.[70] Similarly, the *Civil Code of Quebec* requires that all gamete donations be gratuitous and that any financial reward be restricted to compensation for loss and inconvenience.[71] As a consequence of these laws, the pool of donated material available to infertile couples is significantly reduced, which most likely means increased wait times for many and could even potentially deny some couples access to treatment altogether. For the same reason, these laws serve to reduce patient choice. Canada used to have forty sperm banks nationwide. Now there is only one bank (the Toronto Institute of Reproductive Medicine) and there are currently only approximately thirty to seventy donors.[72] Couples looking for a donor with features similar to their own will have perhaps three options. South Asian couples may only have one option.[73] The laws have thus significantly reduced access and choice, perhaps even to the point of endangering public health as the number of half-siblings from a single donor in a given area increases. Moreover, the laws on surrogacy and gamete donation lack clarity, which has had an impact on access to services. Some clinics that formerly offered ova donation services have suspended their programs because of a lack of legal

[69] *Assisted Human Reproduction Act*, SC 2004, c 2, ss 6-7; *Regulation respecting clinical activities related to assisted procreation*, RRQ 2010, c A-5.01, r 1, s 17; *An Act respecting clinical and research activities relating to assisted procreation*, RSQ 2010, c A-5.01, s 10.
[70] *Assisted Human Reproduction Act*, SC 2004, c 2, s 12.
[71] *Civil Code of Quebec*, RSQ 1991, c 64, s 25.
[72] Roger Collier, "Sperm donor pool shrivels when payments cease" (2010) 182(3) at 109-110.
[73] Roger Collier, "Sperm donor pool shrivels when payments cease" (2010) 182(3) at 109-110; "Semen Donor Catelogue", online: The Toronto Institute For Reproductive Medicine < http://www.repromed.ca/sperm_donor_catalogue> (Accessed 5 June 2011).

clarity over what constitutes "reasonable" expenses for which a donor may be compensated.[74] It is clear that reproductive freedom is restricted by the regulation of IVF.

At the same time, it is not clear that the laws on IVF actually achieve their intended purposes. Given our proximity to the United States where commercial surrogacy and the gamete market are legal and flourishing, it is impossible for the law to eliminate the commercialization of reproduction by Canadian couples. There is also a growing global reproduction market. Many Canadians are choosing to enter surrogacy arrangements in India, Latin America, or the US when they cannot find an altruistic donor.[75] In addition, some clinics have connections to US fertility agencies to facilitate their clients in procuring ova from paid American donors.[76] The ReproMed bank and some fertility clinics will also import purchased donated material from the US for use in Canada.[77] Thus, the ban on commercialization of reproduction at best merely prohibits the sale of Canadian gamete material and Canadian surrogacy services, at the cost of reproductive freedom.

The law which states that only one embryo may be transferred at a time, to a maximum of two or three embryos, depending on the age of the patient, denies women reproductive freedom as well as access to the highest standard of care. As we mentioned earlier, at first glance, this provision seems to be an attempt to improve the quality and safety of IVF procedures by limiting the number of multiple pregnancies that occur. However, this rationale does not consider that the prognosis of infertility differs from patient to patient. Age is one factor in the equation, but so is the particular indicator of infertility. Young women may have reduced egg quality or another condition which would affect the likelihood that a single embryo will implant and result in pregnancy. By restricting the number of embryos entirely by the patient's age, without any discretion given the patient with regard to the patient's actual prognosis, the law denies these women the treatment that is best suited to their condition.

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[74] "Services", online: IVF Canada and Life Program < http://www.ivfcanada.com/services/index.cfm> (Accessed 6 June 2011).

[75] Sharon Kirkley, "Desperate Canadians resort to foreign surrogates" *The Ottawa Citizen*, online: The Ottawa Citizen <http://www2.canada.com/ottawacitizen/news/story.html?id=f19591e1-a773-4bf2-a6b6-597c92a6ce69> (Accessed 7 June 2011).

[76] MacKenna Roberts, "Canada turns a blind eye to egg 'donor' grey market" *BioNews* (22March 2010), online: BioNews <http://www.bionews.org.uk/page_56702.asp> (Accessed 1 September 2011).

[77] "Semen Donor Catelogue", online: The Toronto Institute For Reproductive Medicine < http://www.repromed.ca/sperm_donor_catalogue> (Accessed 5 June 2011).

Moreover, the *Act respecting clinical and research activities relating to assisted procreation* prohibits the transfer of an embryo to a woman who is no longer of childbearing age.[78] This provision denies access to fertility treatment based on age. There is no satisfactory medical justification for this blanket ban. Studies have shown that there is nothing about the postmenopausal uterus that is inhospitable to implantation. The age of the woman may affect the quality of the ova; however, this can be corrected using donated gametes.[79] Some studies have reported lower success rates of IVF in older women or increased complications and health risks in pregnancy and childbirth in older women. However, as other studies have pointed out, these studies fail to take into account the fact that age increases the likelihood that a woman has underlying health problems which may interfere with pregnancy.[80] The law does not take into account these factors. The prohibition applies regardless of a woman's health. The provision is also fairly vague and, depending on how it is interpreted, it may be even more unnecessarily restrictive. "Not of childbearing age" can refer to women who experience early menopause who would not be subject to the same health risks as their older counterparts. Read broadly, it may also apply to women who are perimenopausal, thereby denying access to a huge segment of women who want to reproduce and for whom IVF could be a viable option.

Conclusions

The federal laws struck down by the SCC and existing provincial regulation fail to adequately address the concerns about quality and safety, informed consent, and consumer protection that must be addressed in order to protect vulnerable IVF patients from the inherent risks of the private, for-profit health care sector. The context of privately-finance for-profit delivery, rather than galvanizing greater regulatory force ironically seems to justify across Canadian provinces a "light" regulatory approach. Moreover, even where there is specific IVF regulation, the primary effect of the regulation is not to better regulate quality and safety in the IVF sector but rather to limit the reproductive freedom of women and infertile couples. We conclude with several observations and recommendations for future regulation of the practice.

[78] *An Act respecting clinical and research activities relating to assisted procreation*, RSQ 2010, c A-5.01, s 10.
[79] Richard J. Paulson, et al, "Pregnancy in the Sixth Decade of Life: Obstetric Outcomes in Women of Advanced Reproductive Age" (2002) 288(18) *JAMA* at 2320-2321, 2322.
[80] Richard J. Paulson, et al, "Pregnancy in the Sixth Decade of Life: Obstetric Outcomes in Women of Advanced Reproductive Age" (2002) 288(18) *JAMA* at 2320-2321, 2322.

First, there is a need for regulations that address patient safety and quality of care so that the pressure to achieve a certain profit margin does not result in insufficient or otherwise inadequate (i.e less qualified) staffing, or in practices that exacerbate the risks of IVF in the hopes of obtaining a certain result or attracting more customers. There should also be input regulations that mandate a certain guaranteed standard of care so that the onus is not on the patient to ask about a physician or clinic's qualifications. Likewise, the onus should not be on the patient to research the best standards of care for IVF. Regulation should guarantee such a standard so that patients who may lack knowledge and expertise can trust that they are receiving the best quality of care, despite the economic motives of providers. There should be regulations that set out exactly what is required for consent to IVF to be "informed". Relatedly, there is a need for regulations that focus on consumer protection; specifically, we need regulation on what information ought to be provided. In the case of IVF, there should be more consistency in the reporting and definition of "success rate". Furthermore, there needs to be regulation that addresses the conflicts of interest found in private sector health care that will shield patients from situations where a conflict may arise.

There needs to be a mechanism to enforce these regulations. Enforcement should rely neither on customer complaints nor on self-regulation. Self-regulation tends to be lenient and therefore insufficient. Relying on customer complaints can be ineffective because patients will often not always have the medical know-how to identify when malpractice has occurred or when the law has otherwise been breached. They may not be aware of their legal rights or how to access remedial channels. This relates back to the very information asymmetry that the regulation ought to correct. Moreover, some have suggested that patients are not likely to report a complaint even if they recognize that they have one for fear of jeopardizing the physician-patient relationship. Therefore, there ought to be an independent body that conducts regular evaluations and reports to the government. This body also requires the authority to impose sanctions. It is not desirable to have cumbersome or expensive regulatory requirements that will increase the cost of IVF, placing it beyond the reach of even more individuals. However, a system of regular inspections is not unreasonable in this regard.

Lastly, the government ought to reconsider the effects of the federal bans, the restriction on the number of embryos that may be implanted, and the restriction on the age of IVF patients. More precisely, the government should reassess the purpose of these provisions, and not only

whether that purpose is currently being achieved, but also whether that purpose outweighs the significant restrictions on reproductive freedom that the laws impose. As it stands, the laws on IVF do not guarantee quality and safety, but rather, in some situations, actually work to undermine it. These laws, therefore, ought to be rethought if they are to promote principles of quality and equity in the health care system.