To Govern is to Choose: A Critique of Ontario’s New Plan to Publicly Fund In Vitro Fertilization

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To Govern is to Choose: A Critique of Ontario’s New Plan to Publicly Fund In Vitro Fertilization

Abstract
In December 2015, the government of Ontario introduced the Fertility Program, a plan to publicly fund in vitro fertilization (IVF). The Fertility Program seeks to use the advanced reproductive technology to reduce the occurrence of multiple births and to increase access to fertility treatments. This paper does not argue that IVF should not be publicly funded at all, but rather posits that in a time when the government is restricting healthcare spending, scarce resources must be allocated appropriately. The Ontario government has failed to craft a cost-effective funding program to maximize these limited resources by expanding the role of healthcare to a point that is unsustainable. While the Fertility Program makes steps towards achieving its goals, it fails to implement a comprehensive regulatory scheme and provide financial assistance to those with the greatest need. The province’s failure to provide exclusion criteria to access funding allows the government to escape accountability by deferring public policy decisions to individual fertility clinics. In light of these shortcomings, several reforms to the Fertility Program are suggested and the implications of the Fertility Program going forward have been identified.
INTRODUCTION

In December 2015, the Government of Ontario introduced the Fertility Program, a plan to publicly fund in vitro fertilization (IVF), an assisted reproductive technology. The goals of the Fertility Program are twofold: (1) to reduce the occurrence of multiple births, and (2) to increase access to fertility treatments. This paper does not argue that IVF should not be publicly funded at all, but posits that when a government is restricting healthcare spending, as the Ontario government is currently doing, scarce resources must be allocated appropriately. The Government of Ontario has failed to craft a cost-effective funding program that maximizes limited resources and has instead expanded the role of healthcare to a point that is unsustainable. While the Fertility Program makes steps towards achieving its goals, it fails to implement a comprehensive regulatory scheme and to provide financial assistance to those with the greatest need. Further, the province’s failure to provide exclusion criteria restricting access to funding allows the government to escape accountability by deferring public policy decisions to individual fertility clinics.

This paper proceeds in three parts. Part One begins by providing an overview of IVF as a medical procedure. It next examines the structure of the Canadian healthcare system and details the history of publicly funded IVF in Ontario. It then provides an overview of the Fertility Program. Lastly, it places the Fertility Program within the context of current Ontario healthcare spending and identifies rationales for public healthcare spending that facilitate the appropriate use of scarce resources, such as cost-effectiveness and medical need. Part Two critically analyzes the Fertility Program through the lens of various perspectives, including financial, medical, and social. It demonstrates why three features of Ontario’s Fertility Program do not satisfy the province’s two stated goals, nor the rationales for public healthcare spending identified in Part One. These features are the single-embryo transfer policy, the expenses that are not covered by the Fertility Program, and the age limit of forty-two years for women covered under the Fertility Program. Part Two also considers how the Fertility Program’s failure to impose exclusion criteria impacts when and to whom publicly funded IVF is provided and discusses how clinics should prioritize patients. Part Three identifies the danger of overusing IVF and argues that publicly funded IVF should not be used as a substitute for social programs in cases of naturally declining fertility with
age. The paper concludes by offering suggested reforms, such as mandated data collection and appropriate exclusion criteria, and considers the future implications of the Fertility Program if it proceeds as currently intended.

PART ONE

Understanding IVF

IVF is an onerous procedure involving various healthcare professionals and consisting of four major steps: (1) ovarian stimulation; (2) egg retrieval; (3) fertilization; and (4) embryo transfer. Ovarian stimulation uses fertility drugs, largely composed of hormones, to facilitate the maturation of oocytes in the ovarian follicles. Blood tests and ultrasound imaging are also used at this stage to monitor hormone levels and follicle measurements. Once eggs are sufficiently matured, an injection of the hormone Human Chorionic Gonadotropin (hCG) triggers ovulation. The eggs are then retrieved by guiding a needle through the vaginal wall while the patient is under local anesthesia. Next, sperm is added to the culture dish containing the retrieved eggs to facilitate fertilization. Finally, the resulting embryo(s) are transferred into the uterus through the cervix of the woman who intends to become pregnant. The embryo transfer is done as an outpatient procedure and does not require anesthesia. Any unused embryos can be cryopreserved.

Traditional IVF (as described above) is not suitable for every individual and often requires variations. For example, it is no longer the technique of choice for male factor infertility because of the reduced likelihood of fertilization. Instead, the preferred practice is a specialized form of IVF called intracytoplasmic sperm injection (ICSI), where a single sperm is injected directly into an oocyte instead of bringing the egg and sperm together in a petri dish. ICSI is also used in cases where the male partner is HIV-positive in order to decrease the egg’s exposure to the virus. Assisted hatching, a technique that helps embryos implant in the uterine lining, is recommended

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2 Ibid.
3 Examples of male factor infertility include “low sperm production, abnormal sperm function or blockages that prevent the delivery of sperm”; “Definition of Male Infertility”, online: Mayo Clinic, <www.mayoclinic.org/diseases-conditions/male-infertility/basics/definition/con-20033113>.
5 Ibid at 101.
for women over 37 years of age. Preimplantation genetic screening (PGS) is recommended for women over 35 years of age or in cases of male factor infertility requiring ICSI.

Beyond the arduous procedure outlined above, IVF is a costly financial undertaking. For example, Mount Sinai Hospital in Toronto, Canada charges $7,000 for traditional IVF with an additional $1,500 for ICSI. The first year of cryopreservation for embryos costs $750 with an additional $240 per year thereafter. Fertility medications generally cost between $2,000 and $5,000.

The Structure of the Canadian Healthcare System

The structure of the healthcare system in Canada is largely determined by the Canadian constitution, which sets out the legislative powers and responsibilities of the federal and provincial governments are set out. While “health” is not explicitly listed under sections 91 or 92 of the Constitution Act, 1867, it is implicitly found in several heads of power therein. For example, provinces have exclusive legislative power over the “establishment, maintenance, and management of hospitals,” “property and civil rights,” and “local or private” matters in the province. Together, these heads of power have justified provincial governments’ control over the administration and delivery of healthcare. The federal government has used its constitutional spending powers under subsections 91(1A) and 91(3) to justify the federal enactment of the Canada Health Act (CHA). The CHA sets out the necessary conditions that the provinces must fulfill in order to be eligible for the Canada Health Transfer, which provides healthcare funding on a per capita basis. One such condition is that provincial healthcare plans must be comprehensive, meaning that they must insure all medically necessary services. The CHA neither provides a definition for medical necessity nor a list of services that must

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6 "In Vitro Fertilization", online: Mount Sinai Centre for Fertility & Reproductive Health, <mountsinaifertility.com/patient-resources/types-of-treatments/in-vitro-fertilization/>.
7 “Preimplantation Genetic Diagnosis (PGD)”, online: Mount Sinai Centre for Fertility and Reproductive Health <mountsinaifertility.com/patient-resources/types-of-treatments/prenatal-genetic-diagnosis-pgd/>.
10 The Constitution Act, 1867 (UK), 30 & 31 Vict, c 3, ss 92(7), 92(13), 92(16) [Constitution].
12 Ibid ss 2, 9.
be insured. Instead, provinces are left to individually determine the services they deem medically necessary and, thus, will insure.

The Ontario Health Insurance Act (HIA) categorizes medically necessary services as insurable under the Ontario Health Insurance Plan (OHIP).¹³ A list of these services is provided in Regulation 552 and the Schedule of Benefits.¹⁴ Pursuant to the HIA, the Ministry of Health and Long-Term Care (MOHLTC) reimburses physicians for insured services in the amount negotiated with the Ontario Medical Association (OMA), which represents the interests of Ontario’s physicians.¹⁵ However, this does not preclude provinces from publicly funding services that are not medically necessary. It is within this context—outside of OHIP—that the Fertility Program exists.

The History of Publicly-Funded IVF in Ontario

Prior to 1994, a maximum of three cycles of IVF were insured under the Schedule of Benefits, irrespective of the type of medical infertility diagnosed.¹⁶ In 1993, the MOHLTC and OMA formed the seven-member Joint Review Panel (JRP) to eliminate $20 million in physician spending. The JRP targeted nineteen services, including IVF, for removal from the Schedule of Benefits (often referred to as deinsuring or delisting).¹⁷ The JRP proposed that public funding for all types of infertility except bilateral fallopian tube blockage be delisted from Ontario’s insurance plan, saving $4.4 million in physician expenditures.¹⁸ Other targeted services were the removal of tattoos, acne pimples, and benign skin lesions.¹⁹

In its deliberations, the JRP relied on a 1993 report from the Royal Commission on New Reproductive Technologies (also known as the Baird Commission), which sought to categorize IVF and other reproductive technologies as either effective or

¹³ Health Insurance Act, RSO 1990, c H6 [HIA].
¹⁴ RRO 1990, Reg 552 [Reg 552]; Schedule of Benefits of Physician Services under the Health Insurance Act [Schedule of Benefits].
¹⁵ Ibid; HIA, supra note 13, s 5. See generally “Programs and Services”, online: Ontario Medical Association <https://www.oma.org>. The negotiations between the MOHLTC and OMA have led to multi-year agreements between the MOHLTC and OMA, the latest of which expired in March 31, 2014. The 2012 Physician Services Agreement can be found online at: <www.health.gov.on.ca/en/pro/programs/phys_services/docs/phys_services_agreemnt_en.pdf>. At the time of writing, no new agreement has yet been reached between the MOHLTC and the OMA.
¹⁷ Ibid.
¹⁸ Giacomini et al, “Meaning of Deinsuring”, ibid at 1489; Boyajian, ibid at 331.
¹⁹ Giacomini et al, “Meaning of Deinsuring”, ibid at 1488; Boyajian, ibid at 336.
ineffective. For a technology to be effective, the evidence needed to demonstrate that the procedure would increase the likelihood of a live birth in a woman with that particular diagnosis. Ultimately, the Baird Commission noted that there was not enough evidence available to categorize IVF as effective or ineffective for most infertility diagnoses and that more research should be undertaken. Based on several studies, the Baird Commission concluded that IVF could only be categorized as effective in cases of bilateral fallopian tube blockage. The Ontario government implemented the JRP’s recommendation and amended the regulatory framework to deny funding for IVF in all cases except for bilateral fallopian tube blockage. Unfortunately, no government research initiatives have followed.

The Fertility Program

The status of IVF remained largely unchanged until April 2014, when Kathleen Wynne’s Ontario Liberal government made a pre-election announcement that funding for fertility services would be expanded. In 2015, the government of Ontario allocated funds towards the Fertility Program and confirmed its intention to publicly fund one cycle of IVF. The MOHLTC introduced the Fertility Program on December 21, 2015

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21 Ibid at 518.

22 Ibid at 518-519.

23 Boyajian, supra note 16 at 332; Schedule of Benefits, supra note 15 at V1. Up to three cycles for those with bilateral fallopian tube blockage are insured under Regulation 552, supra note 15, s 24(1)(23). Prior to 1994, IVF itself was not listed in the regulations, but was instead comprised of various procedures. Specifically, two central procedures to an IVF cycle, oocyte retrieval and embryo transfer, were delisted: see Giacomini et al, supra note 16 at 1490. The Health Services Appeal and Review Board (HSARB) has consistently dismissed appeals of the General Manager of the Ontario Health Insurance Plan’s decision to deny IVF funding for other diagnoses. For example, the HSARB denied IVF funding to an applicant whose fallopian tubes were ‘functionally’ blocked due to extensive scar tissue in M.T. v Ontario (Health Insurance Plan), 2006 CanLII 79504 (ON HSARB). The HSARB found that, despite the unlikelihood that anything could get past the scar tissue, the Applicant’s fallopian tubes were technically open.


in 50 fertility clinics and extended eligibility to all causes of infertility. Legislative amendments have removed IVF as an insured service under OHIP and reallocated $20 million in spending from OHIP into the Fertility Program. An additional $50 million from the Ontario budget will fund the Fertility Program.

There are two stated goals under the Fertility Program. First, the Ontario government aims to reduce the occurrence of multiple births. Second, the Fertility Program aims to increase access to fertility treatments. In addition, there are three caveats to the Fertility Program: (1) funding will be provided to women up to the age of 43—or 42 years and 364 days to be precise; (2) ancillary services such as fertility medications and cryopreservation of embryos will not be insured; and (3) the Fertility Program invokes a single embryo transfer policy, where all viable embryos will be transferred one at a time. Apart from these criteria, each clinic is individually responsible for prioritizing patients “using their clinical judgment.”

Identifying Rationales for Public Healthcare Spending to Ensure Appropriate Allocation of Scarce Resources

The Ontario government aims to balance the budget by the 2017-18 fiscal year. The province ran a $10.3 billion deficit in 2014-15, with projected deficits of $5.7 billion and $4.3 billion in 2015-16 and 2016-17, respectively. To reduce the deficit, the government is working to increase revenue while keeping program spending almost flat. Healthcare is the government’s biggest expense, accounting for almost 40...
per cent of its budget. Healthcare spending saw an increase of less than 2 per cent in the last two Ontario budgets, barely keeping up with inflation and an aging and growing population. This gives Ontario “one of the slowest healthcare growth rates in the country.”

The 2015 budget, in which the Fertility Program was first included, marked the fourth year that the Ontario government has made no base budget increases to the province’s hospitals, which, unlike the province, cannot run a deficit by law. These budget freezes have forced hospitals to cut nursing staff, services, and hospital beds. Since February 2015, the province has also cut almost 7 per cent of funding for physician services, which the OMA cites as a “serious threat to quality, patient-focused care.”

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34 *Ibid* at 283, 288. The province’s total expense in 2015-16 was $131.9 billion, of which $50.8 billion was allocated to the Health Sector (38.5%). The province’s total expense in 2016–17 is $133.9 billion, of which $51.8 billion is allocated to the Health Sector (38.7%).

35 See generally the Health Sector budget, *Ibid* at 283: 2012-13: 47.6 billion; 2013-14: 48.9 billion (2.7% increase); 2014-15 50.2 billion (2.6% increase); 2015-16: 50.8 billion (1.2% increase); 2016-17: 51.8 billion (1.7% increase).


37 *Ibid*. Under the *Local Health Systems Integration Act, 2006 (LHSIA)*, SO 2006, c 4 (LHSIA) hospitals must enter into a Hospital Service Accountability Agreement (H-SAA) with their Local Health Integration Network (LHIN) (s. 20(1)), a Crown agent, whose responsibilities include the allocation of MOHLTC funding (s. 5(k)). The LHSIA also requires LHINs to enter into accountability agreements with the MOHLTC (s. 18). The achievement and maintenance of an annual balanced budget is an integral part of the H-SAA: See, for example, s. 6.1.3 of the H-SAA between the South West LHIN and London Health Sciences Centre (LHSC): “Hospital Service Accountability Agreement”, online: LHSC <www.lhsc.on.ca/>. See also, for example, Schedule 4 section 6 of the Accountability Agreement between the Toronto Central LHIN and the MOHLTC: “Ministry-LHIN Performance Agreement”, online: <www.torontocentrallhin.on.ca/>. For information on enforcing HSAAs, see Part III of the *Commitment to the Future of Medicare Act, 2004*, SO, 2004, c 5.


39 OMA, “Ontario budget fails to address growing demand for physician services” *Ontario Medical Association* (25 February 2015) at para 1, online: <https://www.oma.org/Mediaroom/PressReleases/Pages/Ontariobudgetfailstoaddresstargrowingdemandforphysicianservices.aspx>. The annual budget for physician services is $11.6 billion: see Rob Ferguson, “Ontario doctors launch charter challenge over fee cuts” *The Toronto Star* (29 October 2015) at para 8, online: <www.thestar.com/news/canada/2015/10/29/ontario-doctors-launch-charter-challenge-over-fee-cuts.html>. Since no agreement has yet been reached between the OMA and MOHLTC, the 2016 budget does not contain a specific dollar amount that will be allocated to physician services from the healthcare budget: see OMF 2016 Budget, supra note 31 at 197.
While public policy decisions are immune from civil liability, governments remain accountable to the people who have elected them. Constituents depend on the government to undertake the difficult task of managing the public purse, and they rightfully expect their government representatives to govern. Effective management necessitates recognition that the amount of need will always be greater than the availability of resources. Healthcare resources are drawn from the same pool as other social expenses, including education, transportation, and safety. As a result, addressing all healthcare needs would be unsustainable. Instead, rationing is inevitable, necessary, and even desirable.

The distribution of public resources should reflect the values of Ontarians. In allocating scarce healthcare resources, the government must ensure their cost-effective use in order to maximize their value. The effectiveness of a procedure, however, is not the only priority in determining the distribution of public resources. The allocation of scarce resources also necessitates that their use be appropriate. To prevent extraneous spending, a narrow definition of healthcare should be adopted, one that is premised on funding services based on medical need. It is thus appropriate for elective services—the antithesis of medical need—to be paid for out-of-pocket. These categories are not static: what is elective for one person can be necessary for another and vice versa. This understanding of public healthcare spending adopts the biomedical model of health. As opposed to the social model, which is concerned with the broad and underlying determinants of health, the biomedical model focuses on the physical or biological aspects of disease and illness. That is, “health is the absence of disease.” It is within this context of current Ontario healthcare spending that the Fertility Program and its goals will be analyzed and their appropriateness considered.

### PART TWO

**The Goal of Reducing Multiple Births**

In an effort to reduce the occurrence of multiple births, Ontario’s Fertility Program includes a single embryo transfer (SET) policy, as recommended by the June 2015 report of the Advisory Process for Infertility Services (hereinafter the Advisory Report). The Advisory Report cited an average success rate (“clinical pregnancy”) of 25.3 per cent per IVF cycle, with a maximum success rate of 50 per cent depending on various factors, such as the patient’s age. Because of the high out-of-pocket expenses

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40 R v Imperial Tobacco Canada Ltd, [2011] 3 SCR 45.
41 OMF 2016 Budget, supra note 31 at 283.
44 Ibid at 6.
and the low success rate of one IVF cycle, it has become customary to transfer multiple embryos at a time in order to increase the chance of pregnancy. This practice increases the occurrence of multiple pregnancies, with approximately 30 per cent of successful IVF cycles resulting in multiple births, contrasted with a 2 per cent multiple birth rate (MBR) for natural pregnancies.

It is undisputed that multiple pregnancies and births present increased health risks to both the mother and her children when compared with single births. Multiple pregnancies are associated with an increased risk of serious maternal complications, such as gestational diabetes and preeclampsia. Expensive surgeries, such as C-sections and hysterectomies, are three times more likely to be undertaken with multiple births, and post-partum complications, such as haemorrhaging and thromboembolism, are more likely. Moreover, twins experience a shorter gestational period (by three and a half weeks), lower birth weight (by 30 per cent), and higher incidence of stillbirths than singletons. There is also a higher prevalence of permanent disabilities among twins, such as cerebral palsy, and social and language impairments. These complications and procedures are largely managed and carried out in hospitals. Therefore, while IVF has not been publicly funded in Ontario since it was delisted from the Schedule of Benefits in 1994, the high MBR associated with IVF has resulted in immense costs to the public healthcare system. By publicly funding IVF with a SET policy, the Fertility Program aims to reduce these costs.

While a SET is the only way to decrease multiple births, publicly funding IVF is unnecessary in order to achieve this goal. Instead, the government of Ontario could legislatively enforce a SET policy for all fertility clinics in Ontario, as Quebec has done. Such a province-wide policy is especially appropriate because multiple cycles of IVF are often needed before a live birth occurs. Since the Fertility Program only precludes Ontario fertility clinics from transferring multiple embryos when IVF is

45 Kevin S Richter, Robert J Stillman & Eric A Widra, “Moving Toward Single Embryo Transfer” in Ginsburg & Racowsky, supra note 4, at 76.
46 Advisory Report, supra note 43 at 7.
47 Richter, Stillman & Widra, supra note 45 at 77.
49 *Ibid.* at 77-78.
50 See generally MOHLTC “Improving Access”, *supra* note 25.
51 In 2010, the Quebec government undertook to fund up to three cycles of IVF per person, regardless of age. On November 10, 2015, the Quebec government passed *Bill 20, An Act to enact the Act to promote access to family medicine and specialized medicine services and to amend various legislative provisions relating to assisted procreation*, which delisted IVF. Since, the Government of Quebec has implemented various exclusion criteria on public funding, such as denying funding to those who already have one or more children: CBC News, “Quebec in-vitro fertilization: A breakdown of new restrictions on treatment”, *CBC* (13 November 2015) online: <www.cbc.ca/beta/news/canada/montreal/quebec-ivf-treatment-new-law-1.3317682>; *Act Respecting Clinical and Research Activities Relating to Assisted Procreation*, CQLR c A-5.01, s 10.3, as amended by *Bill 20 [Act Respecting Assisted Procreation]*.
public funded, individuals who privately fund the procedure are not bound by the SET policy. Therefore, if the ultimate goal is to reduce multiple births, a comprehensive province-wide policy would be more effective. While several studies indicate that pregnancy rates are significantly lower when a single embryo is transferred, this variance disappears after two SETs where the second transfer is a cryopreserved embryo. The Fertility Program will fund transfers of all such viable embryos at a cost of approximately $1,800 per embryo. A SET is recommended for those under 40 years of age and who have high quality oocytes and embryos. The low effectiveness of a SET cycle of IVF in women over 40 years of age also raises concerns about whether the Fertility Program’s age limit should be lowered. Quebec has accounted for this variance in effectiveness by requiring a SET for women less than 37 years of age and allows for a double embryo transfer for those over 37 years of age at the physician’s discretion.

Finally, it is uncertain whether the Fertility Program is as revenue neutral as the Ontario government purports it to be, since initial estimates required an allotment of approximately $85 million from the Ontario healthcare budget. It is worth recognizing that in 2010, the government of Quebec quickly exceeded its budgeted allowance of $30 million per year for IVF, spending approximately $70 million in 2013.

The Upper Age Limit on the Fertility Program

The Ontario government’s decision to limit the Fertility Program to those who are not yet 43 years of age was influenced by the Advisory Report’s recommendation that IVF should not be publicly funded when the success rate, defined as the occurrence of live births, falls below 10 per cent. Live birth rates for women over 43 years of age are reported to be as low as 5 per cent, compared to 20 per cent for a 40-year-old woman. The predominant reason for this decrease is the quality and quantity of oocytes in a woman’s ovaries and whether they are responding to stimulating hormones.

53 Richter et al, supra note 43 at 76.
54 MOHLTC “50 Clinics”, supra note 26; Sinai Fee Schedule, supra note 8.
55 Richter et al, supra note 43 at 76.
56 Act Respecting Assisted Procreation, supra note 52, s 10.3.
59 Advisory Report, supra note 43 at 10.
60 Khanh-Ha Nguyen & Michael M Alper, “Pre IVF Evaluation of the Infertile Woman” in Ginsburg & Racowsky, supra note 4 at 13 [Nguyen & Alper]; Canadian Fertility and Andrology Society, “Assisted reproductive technologies (ART) in Canada: 2013 results from the Canadian ART Register”, online: <www.cfas.ca/>. Unfortunately, the availability of Canadian data is limited, as discussed below.
which deplete over time. Research from Quebec’s IVF program has shown that the approximate cost to the government for a live birth increases quickly with age. Women aged younger than 35, age 40 and age 43 can incur costs of up to $17,919, $43,153, and $104,000, respectively. These high costs once again raise concerns about the upper age limit of the Fertility Program and suggest that public funding should be offered where it will be most valuable.

The Need for Data Collection

There is, however, disagreement about the correct measure of success to be used in evaluating IVF. The Advisory Report itself contains different measures of success, such as clinical pregnancies and live births, for different propositions. In 1994, the Baird Commission used live births as its measure for success. As previously discussed, IVF was found by the Baird Commission to be effective for one diagnosis only: bilateral blocked fallopian tubes. IVF was not deemed to be ineffective in other cases, such as endometriosis, but the results were inconclusive. Some have argued that the results were inconclusive because live births are not the only way to measure success. For example, a failed IVF cycle can signal that the use of assisted reproductive technologies is futile. This serves as diagnostic information that gives individuals closure and decreases the use of fruitless infertility treatments. Unfortunately, since IVF was delisted from the Schedule of Benefits, there have been no provincial or federal requirements imposed on fertility clinics to report the success rates of the procedure. This results in a lack of information regarding variation between clinics and demographics. It has also been suggested that delisting IVF has resulted in less

61 Nguyen & Alper, ibid at 5, 13.
62 CP “IVF Costs Study”, supra note 53.
63 Advisory Report, supra note 43. For example, success was measured according to live birth rates for determining the maximum age at which a patient would be eligible for public funding (at 10). On the other hand, clinical pregnancy rates were used to determine the general success rate of IVF (at 7).
64 Baird Commission, supra note 20 at 518-519.
65 Giacomini et al, supra note 16 at 1491-1492.
66 Ibid at 1492.
67 Mount Sinai Hospital in Toronto does not report success rates on their website but addresses the issue: “Fertility success rates are complex and difficult to understand without background and context. Due to the fact there are currently no national or provincial requirements with respect to reporting pregnancy rates, it is extremely challenging to provide information in a simple, consistent format for prospective patients to digest in order to determine how a particular clinic compares with other clinics or with the national average”: “Success Rates”, online: Mount Sinai Centre for Fertility & Reproductive Health, <http://www.mountsinai.on.ca/care/fertility/pregnancy-rates/> (accessed 23 September 2015). The Reproductive Care Centre in Oakville, Ontario reports clinical pregnancies for those below 35 years of age, between 35 and 39, and above 40 at ~45%, ~43% and ~22%, respectively. The Fertility Clinic at London Health Sciences Centre reports clinical pregnancies for those below 35 years of age, between 35 and 39, and between 40-42 at 38%, 33% and 24%, respectively: “Pregnancy Rates”, online: London Health Sciences Centre <//www.lhsc.on.ca>. See generally Tom Blackwell, “The fertility clinic guessing
investigation into its effectiveness through randomized trials and studies. This is because patients put less pressure on healthcare providers than the government does to prove that the procedure will work, and patients are often content with the possibility of success.68

Given that the Fertility Program will be predominantly delivered by self-regulated private fertility clinics, the Ontario government should require that all clinics submit data.69 Such data collection would ensure that clinics are providing a high quality of care and would allow the Ontario government to adjust the Fertility Program as needed. These recommendations were contained in the Advisory Report, which advised that data be provided to the BORN-CARTR Plus database, which currently receives yearly data from Canadian fertility clinics on a voluntary basis and calculates national averages.70 The data would then be audited by a Quality Assurance and Improvement Committee and shared with the MOHLTC.71 However, there has been no indication that the Ontario government intends to enforce any requirement for data collection under the Fertility Program.

The Goal of Increasing Access to Fertility Services

While it is likely that the Fertility Program will increase access to fertility services by providing funding to those who would otherwise be unable to access IVF, such assistance will only be helpful to some. The Ontario government has already stated that patients will continue to incur out-of-pocket expenses for embryo cryopreservation and fertility medications. It is unclear whether other services, such as intracytoplasmic sperm injection (ICSI) and preimplantation genetic screening (PGS) will be funded.72 These significant uninsured costs will likely limit Ontario’s goal of expanding access to IVF, possibly resulting in the accessibility of IVF remaining unchanged as the Fertility Program is rolled out.73 This is not a new problem: in 1994, the Panel found that publicly funding IVF was futile. Substantial out-of-pocket costs result in insured IVF being accessible only to the wealthy, who do not need to rely on public funding. Due to this imbalance, the JRP labelled IVF as an “inequitable technology.”74

68 Giacomini et al, supra note 16 at 1492.
69 The MOHLTC has stated that “quality assurance in hospital-based fertility clinics will continue to be managed through the Public Hospitals Act”: see MOHLTC “Improving Access”, supra note 25.
70 Advisory Report, supra note 43 at 7.
71 Ibid at 16-17. The BORN-CARTR Plus database is a collaboration between the Canadian Assisted Reproductive Technologies Registry (CARTR) and the Better Outcomes Registry & Network (BORN) Ontario.
73 Note: this inequity was also acknowledged by the JRP in 1994, as discussed in Part I.
74 Giacomini et al, supra note 16 at 1489-1490.
To address this inequity, a more appropriate program structure would be to provide IVF patients with a tax credit. For example, Manitoba provides a refundable tax credit of up to $8,000, which applies to IVF and related services, such as ICSI and assisted hatching.75 In Quebec, a refundable tax credit is available for IVF and related services based on family income. Families earning less than $50,000 a year are eligible to receive up to 80 per cent of their costs, while those earning over $120,000 can receive up to 20 per cent.76 Calculating funding based on family income allows the provincial government to distribute resources to those who would not otherwise be able to access fertility treatments due to persistent out-of-pocket expenses.

Is Infertility a Disease?

The Ontario government estimates that one in six Ontario couples is affected by infertility during their lifetime.77 However, there is a debate about whether or not infertility is a disease and can thus be classified as a medical need.78 Disease is defined as follows: “[a]n interruption, cessation, or disorder of a body, system, or organ structure or function.”79 Some argue that infertility is actually a symptom of an underlying disease and that a broad application of the term “infertility” is ambiguous because it has been used to describe sterility and fertility that has not lead to conception in a period of one year alike. It is further argued that characterizing infertility as a disease connotes that it is impossible to conceive.80 This is especially troublesome on the fertility end of the spectrum, since it captures individuals who have no underlying condition but who have not conceived for the relatively short period of one year. In these cases, instead of a wait-and-see approach, a prognosis that requires immediate treatment is attached to the diagnosis of infertility.81 In the context of an expensive, advanced technology procedure like IVF, this can lead to premature treatment that

75 Manitoba, Government of Manitoba Finance, “FAQ’s About the Fertility Treatment Tax Credit”, online: <www.gov.mb.ca/finance/tao/fttc_faq.html >.
76 “Quebec In-Vitro Fertilization: A Breakdown of New Restrictions on Treatment”, CBC News (13 November 2015) online: <www.cbc.ca/beta/news/canada/montreal/quebec-ivf-treatment-new-law-1.3317682 >. See also Revenu Québec, “Tax credit for the Treatment of Infertility”, online <www.gouv.qc.ca> (Quebec imposes a cap on its tax credit equal to 50% of expenses up to $10,000 a year).
77 MOHLTC “Improving Access”, supra note 25.
79 Stedman’s Medical Dictionary, (online: www.drugs.com) sub verbo "disease". Note: disease is synonymous with illness. Stedman’s Medical Dictionary, (online: www.drugs.com) sub verbo "illness".
81 Ibid.
ultimately would not increase the likelihood of conception when compared with no
treatment.\textsuperscript{82} This is, therefore, an inappropriate use of Ontario’s scarce resources.

\textbf{When is IVF Medically Indicated as a Treatment for Infertility?}

In conceptualizing IVF as a treatment for the “disease” of infertility, evaluating
its suitability is not a question of whether or not IVF would lead to the desired outcome
of bearing a child. Instead, the focus should be on whether the procedure is medically
indicated. A medical indication is defined as follows: \textit{“[t]he basis for initiation of a
treatment for a disease or of a diagnostic test, [which] may be furnished by a knowledge
of the cause (causal indication), by the symptoms present (symptomatic indication), or
by the nature of the disease (specific indication).”}\textsuperscript{83} Characterizing infertility as
medically indicated is problematic because it justifies resolving childlessness instead of
any underlying disease.\textsuperscript{84} For example, recurrent pregnancy loss, which is defined as
three consecutive miscarriages, is a type of infertility where a woman cannot achieve a
successful live birth. Recurrent pregnancy loss infertility has many causes, including
uterine fibroids, which are benign tumours that form in and around the uterine wall.\textsuperscript{85} In
some cases, uterine fibroids can negatively affect IVF outcomes. Research has found
that small uterine fibroids lowered the rates of implantation, pregnancy, and live births,
and that they increased the rate of miscarriages. While it is unclear whether removing
small uterine fibroids (the procedure is called a myomectomy) would ameliorate IVF
outcomes, a myomectomy of large uterine fibroids has been shown to increase
pregnancy rates and decrease miscarriage rates.\textsuperscript{86}

Another illustrative example is endometriosis, a disorder where endometrial
tissue, which ordinarily lines the uterus, grows outside of it. Endometriosis can decrease
the likelihood of pregnancy when scar tissue blocks an egg from leaving the ovaries or
entering the fallopian tubes.\textsuperscript{87} In cases of endometriosis-associated infertility, treating
the underlying endometriosis through surgery can also alleviate the symptom of
infertility.\textsuperscript{88} Research has found that while a combination of surgery and IVF achieve
the highest likelihood of pregnancy, surgery should be the primary course of action
because of its efficacy in treating endometriosis and its related infertility. Meanwhile,

\begin{itemize}
\item \textsuperscript{82} Note: this is the definition the Baird Commission used for effectiveness.
\item \textsuperscript{83} \textit{Stedman’s Medical Dictionary}, (online: www.drugs.com) \textit{sub verbo} “indication”.
\item \textsuperscript{84} Richard P Dickey et al, “Infertility is a Symptom, Not a Disease” (2000) 74:2 Fertility and Sterility 398
at 398.
\item \textsuperscript{85} “Causes of Female Infertility”, \textit{Heartland Fertility & Gynecology Clinic}, online:
<heartlandfertility.mb.ca/en/infertility/causes-of-female-infertility/> ["Female Infertility"].
\item \textsuperscript{86} Y Khalaf et al, “The Effect of Small Intramural Uterine Fibroids on the Cumulative Outcome of
\item \textsuperscript{87} "Female Infertility", \textit{supra} note 85.
\item \textsuperscript{88} Pedro N Barri et al, “Endometriosis-Associated Infertility: Surgery and IVF, a Comprehensive
\end{itemize}
the efficacy of solely using IVF as a treatment was significantly lower than that of surgery. Therefore, IVF should be provided as a complementary therapy if surgery on its own does not alleviate the symptom of infertility.\footnote{Ibid at 180-181, 183.}

The Government of Ontario has not provided guidelines for assessing a patient’s eligibility for public funding. It is unclear whether the Fertility Program will require women to undergo treatment for the underlying cause of infertility before they are able to access insured IVF. Under Quebec’s legislative framework, physicians must ensure that IVF is preceded “by a period of sexual relations or a number of artificial inseminations.”\footnote{Act Respecting Assisted Procreation, supra note 45, s 10.3.} Such guidelines would ensure that public funding would only be provided when IVF is deemed appropriate and is not premature.

**The Case of Social Infertility**\footnote{The term “social infertility” refers to non-medical forms of infertility. This category of IVF patients encompasses same-sex couples and single people.}

The Ontario government has stated that the Fertility Program will provide access to publicly funded IVF “regardless of sex, gender, sexual orientation or family status.”\footnote{MOHLTC “Improving Access”, supra note 25.} This avoidable use of limited funds stretches the definition of healthcare far beyond the biomedical model. The result is that two groups, medically fertile same-sex couples and single individuals, are given a publicly insured medical procedure without a medical indication.

Fertile lesbian couples are increasingly using IVF to allow both partners to biologically participate in the reproductive process. This is done through a technique called ROPA (Reception of Oocytes from PArtnert), where embryos created using the oocytes of the other partner are implanted in each woman.\footnote{S Marina et al, “Sharing Motherhood: Biological Lesbian Co-Mothers, a New IVF Indication” (2010) 25:4 Human Reproduction 938 at 940.} Another technique involves the fertilization of one partner’s eggs, which are subsequently implanted into the uterus of the other partner to carry.\footnote{Marilynn Marchione, “Fertility Clinics Aiding Same-Sex Couples; ‘2-Mom’ Approach Lets Both Share Biological Role”, Global News (16 October 2013) online: <globalnews.ca/news/905073/fertility-clinics-aiding-same-sex-couples-2-mom-approach-lets-both-share-biological-role/>.} Finally, both partners could provide oocytes to be fertilized. The resulting embryos would then be implanted in one or both partners, essentially leaving up to chance whose egg will result in a successful pregnancy. However, fertile lesbian couples can use less expensive methods, such as intrauterine insemination (IUI), where sperm is inserted into the uterus to facilitate fertilization.\footnote{IUI costs approximately $500: see Sinai Fee Schedule, supra note 8.}
Fertile single women also have the option of using IUI instead of IVF to conceive. On the other hand, gay couples and fertile single men almost exclusively use IVF with a surrogate in order to reproduce because other forms of assisted reproduction are not available to them. Because the socially infertile can turn to IVF from the outset of their pursuit—or soon thereafter—of having a child, they may access insured IVF under the Fertility Program before the medically infertile, who often try other assisted reproductive technologies prior to using IVF. This means that those with a medical indication for IVF may not have an opportunity to access funding before the already limited resources are depleted.

The appropriate allocation of public healthcare resources was addressed in Cameron v Nova Scotia (Attorney General), where the Nova Scotia Court of Appeal (NSCA) addressed a constitutional challenge to the decision of the Nova Scotia government to exclude IVF and ICSI from its list of insured services. In their factum, the respondents distinguished between medical and non-medical means and ends, and placed them within a matrix:

There are four categories in this matrix: medical means to medical end (e.g., surgical removal of an intestinal blockage); non-medical means to a medical end (e.g., alleviation of poverty); medical means to a non-medical end (e.g., growth hormone for a boy who is expected to grow to be 5'6" so that he will grow to be 6'4" and have a better likelihood of a basketball career); and non-medical means to a non-medical end (e.g., basketball lessons for the 5'6" boy). In the context of the provision of health care services, “medically necessary” must capture the first category and only the first category, i.e., medical means to medical ends.

Within this framework, IVF for the socially infertile is a medical means to a non-medical end—a child—and is more analogous to an elective procedure than a necessary

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96 There is an emerging trend of “virgin births” in the United Kingdom (UK) where young (in their 20s), single women who have never been in a sexual relationship are using IVF to have a child. These women have all privately paid for IVF, as the procedure is not publicly funded in the UK. Interestingly, these do not mirror the typical demographics of single women who access IVF: women who are over thirty-five years of age and have not conceived in order to further their careers. It is, therefore, unclear where ‘virgin births’ would fit within the Canadian context. See Laura Donnelly, “British women paying $10,000 each to have ‘virgin births’ and save sex for later”, The Telegraph (27 September 2015) online: National Post <www.news.nationalpost.com>.

97 Gay couples can use IUI with a surrogate. However, issues surrounding the legal rights of the gay couple as parents of the resulting child arise because surrogate is genetically, and therefore legally, the child’s mother. See “Same-Sex Parents and the Law”, online: Educaloi <https://www.educa loi.qc.ca>.

98 1999 CarswellNS 266, 1999 NSCA 14 [Cameron]. The challenge was based on equality under section 15(1) of the Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11 [Charter].

99 Cameron, ibid at para 84. While this analysis was made within the context of defining “medical necessity” under the Health Services and Insurance Act, RSNS 1989, c 20, it provides a helpful framework within which we can place social infertility.
one. Recall here that IVF was grouped with several clear examples of elective procedures targeted for delisting in 1994. In the end, the NSCA in Cameron found the appellants’ equality right had been infringed, but the infringement was justified because the objective of the impugned Nova Scotia legislation was to provide the highest quality of healthcare possible with limited financial resources. Cameron once again reminds us that governments must give careful consideration in distributing scarce resources. Therefore, it is difficult to justify the indiscriminate delivery of publicly funded IVF to the socially infertile without first prioritizing medical infertility in light of Ontario’s limited healthcare resources.

How Should Clinics Prioritize Patients?

The Ontario government has provided fertility clinics with little guidance on how to prioritize patients. Instead, clinics are left to create their own systems “using their clinical judgment.” As a result, inconsistent approaches have been adopted across the province, which include first-come-first-serve, lottery, case-by-case, and triage methods. Triage, which “generally takes those who are most likely to succeed,” may encourage clinics to create their own exclusion criteria, such as age, despite the Fertility Program’s broad mandate. Other clinics might use the matrix in Cameron: this would favour a fertile heterosexual couple conceiving with IVF to take advantage of PGS (for example, to test for genetic diseases or identify a bone marrow match) over a socially infertile couple because PGS achieves a medical end. By failing to regulate

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100 Giacomini et al, supra note 16 at 1493. These elective procedures included the removal of tattoos, acne pimples, and benign skin lesions

101 Cameron, supra note 98. The infringement was justified under section 1 of the Charter, which reads: “The Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society”: Charter, supra note 91.

102 MOHLTC Q&A, supra note 30.


105 MM Peterson, “Assisted reproductive technologies and equity of access issues” (2005) 31 Journal of Medical Ethics 280 at 282. The ethics of using IVF to create “designer babies” is a controversial topic, especially when discussing the ethics of altering a child’s aesthetic features. For example, see: BBC Technology, “23andMe’s ‘build-a-baby’ patent criticised” (3 October 2013), online: BBC News
the distribution of funding under the Fertility Program, the Ontario government is able to insulate itself from the controversial and difficult decisions that will undoubtedly need to be made.

The Lack of Exclusion Criteria under the Fertility Program

The Government of Ontario has also failed to impose exclusion criteria under the Fertility Program based on contraindications. Contraindications are defined as: “[a]ny special symptom or circumstance that renders the use of a remedy or the carrying out of a procedure inadvisable, usually because of risk.”106 The Advisory Report recommended that those who score higher than ASA 2 under the American Society of Anaesthesiologists’ classification system—meaning a body mass index (BMI) of over 30—should not be eligible for egg retrieval “for safety reasons.”107 Morbid obesity, a history of cardiac malformation, and exposure to infectious diseases can all put patients at an “unacceptably high risk” for complications during pregnancy and are therefore seen as contraindications to pregnancy.108 A BMI greater than 30 also significantly lowers the rate of achieving pregnancy.109 However, the Ontario government did not adopt the Advisory Report’s recommendation.

The lack of exclusionary criteria coupled with the Fertility Program’s administration outside of OHIP raises important implications for physician decision-making. Recently, National Post columnist Barbara Kay asked the following question: “Are women seeking IVF patients or clients?”110 Within the context of the Fertility Program, the question, however, is a little more nuanced: Are women seeking publicly-funded IVF patients or clients? The question should not ask whether a specific category of individuals should undergo IVF, but should instead focus on maximizing healthcare funds allocated to the Fertility Program. This can be done by providing publicly funded IVF to a much narrower category of individuals, based on both medical need and cost-efficiency. The province’s failure to impose exclusion criteria renders individuals seeking publicly-funded IVF more analogous to clients than patients because it forces doctors to make policy decisions, not strictly medical decisions. For example, a fertility clinic might prioritize a woman who is approaching her forty-third birthday and has not

106 Stedman’s Medical Dictionary, (online: www.drugs.com) sub verbo “contraindication”.
107 Advisory Report, supra note 41 at 10; “ASA Physical Status Classification System”, online American Society of Anesthesiologists <www.asahq.org/resources/clinical-information/asa-physical-status-classification-system >.
108 Nguyen & Alper, supra note 55 at 3.
109 Ibid.
110 Barbara Kay, “IVF for obese women is a wish, not a right”, National Post (5 May 2014), online: National Post <news.nationalpost.com/full-comment/barbara-kay-ivf-for-obese-women-is-a-wish-not-a-right > [emphasis in original].
exhausted all other fertility treatments over someone who is 25-years-old and using IVF as a last resort. This sort of triage does not rely on prognosis, but treats IVF as a social service as opposed to a medical procedure.

PART THREE

The Danger of Overusing IVF

IVF has been proven to have long-term effects on the health of both mother and child. Women who undergo IVF may experience ovarian hyper-stimulation syndrome (OHSS), a potentially life-threatening complication of ovarian stimulation, ectopic pregnancies, or cancer.111 Children born from IVF may experience elevated blood pressure and glucose levels.112 Children born from ICSI may have a higher incidence of congenital malformations (5.2 per cent) compared to that of the normal population (2 per cent).113 Here, the concern is not that IVF and ICSI come with risk factors, as most medical interventions do, but instead with whether IVF is being overused and should be limited to more obvious medical forms of infertility. There has been significant concern about using IVF for unexplained fertility, which accounts for approximately one-quarter of all individuals seeking IVF, because conception often occurs spontaneously after the one-year mark for these couples.114 Once again, the concern is that an onerous and costly procedure such as IVF is being used prematurely and unnecessarily.

IVF Should Not Be a Substitute for Social Prevention

Finally, the expansion of healthcare beyond the biomedical model also arises in the context of women over 35 years of age. In his analysis, author David Goldhill illustrated this by using Viagra, a medication used to treat erectile dysfunction, as an example.115 He noted that before Viagra was created, erectile dysfunction was a natural outcome of aging. Goldhill questioned whether this would be a health issue for which governments envisioned public funding. Within this context, he argued that managing conditions without curing them has led to the expanded role of healthcare.116 Goldhill’s analysis applies equally to women, since their fertility naturally decreases as they age.

113 Mahmoud, supra note 112 at 245. The link between ICSI and various risks has been disputed: Palermo, supra note 4 at 109-110.
114 Kamphuis et al, supra note 113 at 1.
116 Ibid.
While the value in managing the side effects of aging is not disputed, the conditions for which Viagra and IVF are used should be contrasted with medications for arthritis or hypertension, which are also associated with aging but are more traditional examples of appropriate public healthcare expenses. Similarly, some scholars question whether IVF is being improperly used to address a social problem. They argue that women currently experience societal pressures, such as career advancement, which result in delayed attempts to start a family. Instead, they provide recommendations aimed at facilitating family building, an underlying goal of the province’s Fertility Program, within the period of natural fertility. Once again, it is unclear whether publicly funding IVF can be justified as a solution to treat a symptom (infertility) while not treating or curing the underlying condition (societal pressures to delay pregnancy).

CONCLUSION

The preceding discussion illustrates how publicly funding IVF raises many complex multidisciplinary issues. Ultimately, the Fertility Program’s design simultaneously goes too far and not far enough. While the SET policy under the Fertility Program will reduce multiple births, it only targets multiple births in the context of publicly funded IVF. Instead, the Ontario government should go further and legislatively impose a province-wide SET policy, addressing multiple births for all IVF procedures, regardless of who is paying the bill. Moreover, substantial out-of-pocket costs, such as fertility drugs, will continue to render IVF inaccessible to many. Instead, a refundable tax credit for IVF and related services based on family income would be more appropriate.

The Fertility Program also fails to address several key issues. Most notably, the lack of exclusion criteria results in a funding program that is neither cost-effective nor well-defined. The province should provide fertility clinics with more guidance on prioritizing patients, instead of having them rely on their individual “clinical judgment.” As an expensive advanced reproductive technology, IVF should be a last resort for couples seeking government funding. Thus, a concise functional definition of infertility should be created for the Fertility Program. Such guidelines should require, for example, a minimum number of failed artificial inseminations, or that underlying causes of infertility be treated first. Moreover, medical infertility should be prioritized to ensure that the use of public healthcare resources is medically indicated and not to facilitate biological participation in family-building. Exclusion criteria, such as a high BMI, should be enforced to allocate funding where it is most likely to succeed. While

117 Ibid.
119 Ibid at 477.
the Ontario government has set an upper age limit under the Fertility Program, the low effectiveness of IVF in women over 40 years of age suggests that the age limit should be lowered to maximize healthcare funds. Finally, funding should be denied to those who already have one or more children.

As the Fertility Program continues to roll out, the Ontario government should require fertility clinics to submit clinical data for quality assurance and to identify any adjustments needed to increase the Fertility Program’s effectiveness. Moreover, research into the long-term risks of IVF should be completed to ensure that the procedure will not result in future harm to both mother and child. Finally, programs that decrease societal pressure for women, such as childcare, should be implemented alongside the Fertility Program to decrease the use of IVF by women who have declining fertility.

While this paper focuses solely on IVF and healthcare spending, the above discussion has far-reaching and important implications for government expenses generally. In a time when spending is restricted, it is especially important for the government to make appropriate decisions and be transparent in that process. As key stakeholders in the province, Ontario’s citizens must keep the government accountable to ensure future sustainable healthcare for all.