ASSISTED REPRODUCTION AND RESEARCH ON HUMAN EMBRYOS: RESPECTING CANADIAN VALUES WHILE PROMOTING RESEARCH TO ADVANCE HEALTH

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CASE PRESENTATION

Background

Assisted reproductive technologies (ART) aim to improve the outcome of human reproduction, whether by increasing the chances of a pregnancy (e.g. IVF), or allowing access to information about the genetic makeup of embryos (e.g. PGD) or fetuses (e.g. prenatal testing). In the future, these technologies may allow the genetic modification of gametes (sperm or egg) and embryos via gene editing for the purpose of preventing disease. While the purported aim of such technologies is informed decision-making and reproductive success, with all the associated benefits, certain uses are nevertheless controversial. Apart from the beneficial impact on fertility, certain aspects of ART can be seen as negatively impacting certain stakeholders, such as those children conceived as a result of ART, prospective mothers, the donors of required genetic material, and more indirectly people living with those disabilities that can be selected against by genetic testing.

With advances in ART in the late 20th century came societal debates on the acceptability of using technology in the context of human reproduction. Contrary to other biomedical technologies, ART affects not only its users, but also future individuals whose conception, and hence identity, depends on the decisions made by their progenitors, constrained by social policies regulating certain interventions. Under the guise of protecting certain vulnerable populations, but undoubtedly also moved by other considerations, Canadian lawmakers engaged in lengthy deliberations that resulted in 2004 in the *Assisted Human Reproduction Act* (AHRA) becoming law.

The present case study explores the events unfolding before and after the passing of the *Act*, from 1989 until 2013 and beyond, with a particular focus on how the problem was set up (what reasons for enacting regulation were given, what evidence was presented) and on how well its objectives were achieved. It concludes by offering an analysis of how the Act aligns with its stated principles and some suggestions for improvement going forward.

Setting the Agenda (1989-1995)

In 1989, the Royal Commission on New Reproductive Technologies was established in Canada. In 1993, the Commission[1] issued its final report, titled "*Proceed with Care*" (Government of Canada, 1993). The report called for "Criminal Code prohibitions on selling human eggs, sperm, zygotes, or fetal tissue; advertising for, paying for, or acting as an intermediary for preconception (surrogacy) arrangements; using embryos in research related to cloning, creating animal/human hybrids, fertilizing eggs from female fetuses for implantation; and unwanted medical treatment or other interference with the physical autonomy of pregnant women", as well as creating the "National Reproductive Technologies Commission (NRTC) to oversee licensing and to monitor reproductive technologies and practices".

Two years later, the federal Minister of Health Diane Morleau announced an interim moratorium on "sex-selection for non-medical purposes; commercial preconception or "surrogacy" arrangements; buying and selling of eggs, sperm, and embryos; egg donation in exchange for in vitro fertilization (IVF) services; germline genetic alteration; ectogenesis (creation of an artificial womb); the cloning of human embryos; formation of animal-human hybrids by combining animal and human gametes; and the retrieval of eggs from cadavers and fetuses for donation, fertilization or research" (Baylis & Herder, 2016).

The Assisted Human Reproduction Act (1996-2004)

In 1996, to address the concerns outlined in the report, Bill C-47 (*The Human Reproductive and Genetic Technologies Act*) was introduced into the House of Commons by Minister of Health David Dingwall, but died due to a federal election being called. Then, in 2002, Bill C-56, *An Act respecting assisted human reproduction*, was introduced into the House of Commons, but also died due to Parliament being prorogued in 2002. A month later, Bill C-56 was reinstated as Bill C-13, and becoming Bill C-6, in 2004, completed all legislative stages and on March 29th, received Royal Assent and became law as the *Assisted Human Reproduction Act* (Baylis & Herder, 2016).

The law declares the principles guiding its formulation, and goes on to prohibit, under penalty of criminal sanctions, certain uses of ART and regulate others. The uses of ART prohibited by *AHRA* in Canada include:

> 1) creating "a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device";
> 2) creating "an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures";
> 3) creating "for the purpose of creating a human being, […] an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being";

[1] consisting of Patricia A. Baird, Grace M. Jantzen, Bartha Maria Knoppers, Susan E.M. McCutcheon, and Suzanne Rozell Scorsone

4) maintaining "an embryo outside the body of a female person after the fourteenth day of its development following fertilization or creation, excluding any time during which its development has been suspended";
5) "for the purpose of creating a human being, perform[ing] any procedure or provid[ing], prescrib[ing] or administer[ing] any thing that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an in vitro embryo, except to prevent, diagnose or treat a sex-linked disorder or disease";
6) "alter[ing] the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants";
7) "transplant[ing] a sperm, ovum, embryo or foetus of a non-human life form into a human being";
8) "for the purpose of creating a human being, mak[ing] use of any human reproductive material or an in vitro embryo that is or was transplanted into a non-human life form";
9) "creat[ing] a chimera, or transplant[ing] a chimera into either a human being or a non-human life form"; and
10) "creat[ing] a hybrid for the purpose of reproduction, or transplant[ing] a hybrid into either a human being or a non-human life form" (*Assisted Human Reproduction Act*, 2004).

In addition, the *AHRA* prohibits using gametes or in vitro embryos without the consent of the donor, obtaining gametes from a minor unless it is for "the purpose of preserving the sperm or ovum or for the purpose of creating a human being that the person reasonably believes will be raised by the donor", for example in the case of childhood diseases affecting fertility (or whose treatment affects fertility), or participating in any economic activity resulting in donors of gametes, in vitro embryos or other reproductive material or surrogate mothers being paid. In relation to the last point, the *Act* specified separately (p.12) that "[n]o person shall, except in accordance with the regulations", reimburse a donor or surrogate mother for expenditures incurred in relation to donating or surrogacy.

In 2006, the *Assisted Human Reproduction Canada (AHRC)* agency was established in order to administer the *AHRA*.

Provincial Appeals, Supreme Court Rulings, and Amendments to the AHRA (2006-2012)

In 2006, the Attorney General of Quebec, joined by the Attorneys General of New Brunswick, Saskatchewan, Alberta and the Canadian Conference of Catholic Bishops and Evangelical Fellowship of Canada, filed an appeal to the Supreme Court of Canada (SCC) claiming the *AHRA* violated the 130-year status quo of the right of provinces to regulate health care (Supreme Court of Canada, 2010).

In 2010, the SCC released its decision that some of the Act's contested sections were unconstitutional, but upheld remaining sections. In summary, the court upheld the status quo of provinces regulating health care, and particularly fertility clinics, but confirmed that prohibiting

certain uses of ARTs as well as payment of donors or surrogate mothers by the federal government was constitutional.

To implement the court's decision, the federal government (Bill C-38) made amendments to *AHRA* in 2012, repealing certain sections detailing prohibited activities as well as all sections detailing the responsibility of the Minister for administering the law, except for the first that states that the Minister "is responsible for the policy of the Government of Canada respecting assisted human reproduction and any other matter that, in the opinion of the Minister, relates to the subject-matter of this Act", and a few sections relating to "Administration and Enforcement", among others (*Assisted Human Reproduction Act*, 2004).

During all this, the *AHRC* agency was beset with criticism, culminating in three board members[2] quitting in 2010, claiming that the agency was mismanaged and allocated funds ($5 million annually) misspent, even before the *AHRC*'s mandate was overturned by the SCC, relegating some responsibilities to the provinces. In particular, the agency was accused of ignoring violations of *AHRA*, with "considerable evidence of commercial transactions in Canada (Motluk, 2010; Blackwell, 2013) for both surrogacy and human eggs (Downie & Baylis, 2013; Drummond & Cohen, 2014), and yet our research reveals that there has only been one conviction in the last ten years" (Snow et al., 2015). Snow et al. (2015) accuse the Canadian government (under Stephen Harper, 2006-2015) of being motivated to "keep debates regarding access to abortion and the status of the fetus out of Parliament" as well as "to avoid any debate on policy issues that touched on human reproduction, assisted or otherwise". It is in such a political climate that *Health Canada* consistently delayed issuing regulations to administer *AHRA* (Cattapan, 2013). Finally, as part of the above-mentioned amendments to the *Act* by the federal government in 2012, the *AHRC* agency was abolished and responsibility for enforcing *AHRA* fell to *Health Canada*.

Revisiting AHRA

Although "the bill provides for a three year review" (House of Commons, 2002) by the House of Commons or the Senate, no such review was ever conducted. In 2017, building on arguments that "criminalization may cause more harm than good by creating inflexible rules that do not leave much room for provincial regulation or cooperative national regulation between the federal and provincial governments" (Ogbogu, 2013), a group led by the same Dr. Knoppers who participated in drafting the 1993 report *Proceed with Care* published an editorial in *Nature Regenerative Medicine* calling for revisiting *AHRA* and, in particular, for *Health Canada* to issue clarifications to the *Act* allowing germline gene editing in the context of pre-clinical research (Knoppers et al., 2017).

[2] Françoise Baylis, Barbara Slater and Irene Ryll

DEFINING THE PROBLEM AND PROPOSING SOLUTIONS

Defining the Problem: Underlying Values and Assumptions and "Consensual Evidence"

The *AHRA* was presented as "a legislative framework to protect the health and safety of Canadians and their offspring" and as a law that "would, at the same time, offer new hope for infertile people, as well as those suffering from illness and disease." (Anne McLellan, House of Commons, 2002) The law explicitly laid out seven principles that guided its drafting:

> 1) the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use;
> 2) the benefits of assisted human reproductive technologies and related research for individuals, for families and for society in general can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies and in related research;
> 3) while all persons are affected by these technologies, women more than men are directly and significantly affected by their application and the health and well-being of women must be protected in the application of these technologies;
> 4) the principle of free and informed consent must be promoted and applied as a fundamental condition of the use of human reproductive technologies;
> 5) persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their sexual orientation or marital status;
> 6) trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition; and
> 7) human individuality and diversity, and the integrity of the human genome, must be preserved and protected. (*Assisted Human Reproduction Act*, 2002)

Transcripts of parliament sessions in which the bill was discussed by members of parliament (MPs), reveal additional nuance as to the values and assumptions underlying these stated principles. In addition to resorting to generic "Canadian values" or "respect [for] human life and health, as well as the integrity of our human genetic make-up" (Anne McLellan), MPs also voiced their concerns and fears behind the motivations for this bill. For example, Réal Ménard stated:

> [t]his bill is about a situation unprecedented in the history of humankind. For the first time ever, it will be possible to procreate without having sexual relations. With the new reproductive technologies, the conventional scenario whereby a man and a woman must have sexual relations in order to have children has changed. Not only will there be a divorce and a disconnect between sexuality and procreation, but it will also be possible for a child to be the product of two parents who do not know each other and who have never met. From the point of view of ontology and the human condition, these are

> important facts in understanding why we want the new reproductive technologies sector to be legislated and what kind of legislation we want. (House of Commons, 2002)

We thus see that, at least for some, the main motivation is protecting what they see as the 'natural way' of reproducing. We can assume that this 'natural way' is consistent with patrilocal nuclear family arrangements based on genetic relatedness, falsely presented as "the human condition". Anne McLellan, in her opening remarks, claims that Bill C-56 "is important because it will fill a void. At present, Canada has no law to prohibit or regulate activities relating to assisted human reproduction. And it is equally important, because these issues are not easy ones. Nor should they be, as they go to the very heart of our values as a society, with regard to the way we build our families." (House of Commons, 2002)

It is worth noting that although protecting "the way we build families" was cited several times by MPs as one of the primary values driving this legislation, it is nowhere to be found explicitly in the principles outlined at the beginning of the Act. That these assumptions did not become principles cited in the law may indicate that they were so taken for granted by MPs that they are not aware of holding them. However, a historic analysis of how *AHRA* came into existence requires questioning such assumptions, as is often done by academic disciplines such as normative ethics and anthropology, who challenge the notion that a child being "the product of two parents" is inherent to "human nature".

For example, classical anthropologists of 19th century Europe all concurred that "early humans" did not take one mother and one father as the basic unit of kinship in society, instead relying on cooperative childcare (Hrdy, 2011). On the other hand, these anthropologists also believed that the "nuclear model" of "civilized" Victorian Europe was superior to the "group motherhood" (Freire-Marreco, 1914; Eggan, 1950) originally practiced by humans. The consensus regarding cooperative childcare among all early human societies was then rejected during the 20th century by leading Western anthropologists. Malinowski explains his rejection of the "group motherhood" hypothesis:

> I believe that the family and marriage from the beginning were individual. You will remember that I laid great emphasis on the fact that maternity is individual. A whole school of anthropologists, from Bachofen on, have maintained that the maternal clan was the primitive domestic institution, and that, connected with this, there was group marriage or collective marriage. In my opinion, as you know, this is entirely incorrect. But an idea like that, once it is taken seriously and applied to modern conditions, becomes positively dangerous. I believe that the most disruptive element in the modern revolutionary tendencies is the idea that parenthood can be made collective. If once we came to the point of doing away with the individual family as the pivotal element of our society, we should be faced with a social catastrophe compared with which the political upheaval of the French revolution and the economic changes of Bolshevism are insignificant. (1956)

Another assumption underlying the debate was exemplified in the words of Rob Merrifield:

> I want to state my belief that every Canadian, young and old, has been endowed with an intrinsic value by their creator. Human life is special and I am in favour of protecting and preserving human life at all stages, from conception to natural death. Scientists largely agree with the technical moment of when life begins. All indications are that life begins at conception. For example, our personal DNA structures will remain unchanged from conception to death. There is no logical stopping point after conception where we can say that life begins. There is overwhelming agreement on this question. (House of Commons, 2002)

Paul Szabo also refers to the allegedly "uncontested biological fact", which is, in fact, vigorously contested in contemporary debates on the matter, by citing Dre. Françoise Baylis' testimony to the *Standing Committee on Health* on May 31, 2002: "The first thing to recognize in the legislation and in all of your conversations is that embryos are human beings. That is an uncontested biological fact. They are a member of the human species." (House of Commons, 2002)

It is curious that MPs present contentious issues as garnering "overwhelming agreement" or constituting "uncontested biological facts". Arguably, such "facts" were presented to coincide with their own personally held beliefs. As Timothy Caulfield notes in his commentary on the *Act*:

> policy-makers should not justify personal positions based on a non-existent public consensus and must recognize that a call for a more restrictive research environment is counter to the current public ethos. The calls for tighter restrictions of stem cell research and therapeutic cloning are often justified, implicitly or explicitly, by appeal to social consensus. But this consensus clearly does not exist. (2002)

Another value – that "[a]ll Canadians should benefit equally from improvements to infertility treatment" – was cited by M.P. Judy Wasylycla to criticize *AHRA*, which did not address the issue of equity of access to ARTs. Aiming for complete equity of access to ARTs could be seen as a threat to the profitability of fertility clinics. Taking the latter's interests into consideration, as decision-makers are expected to, could have played a role in the value of equity of access being neglected in drafting the law.

DISCUSSION: DO THE AHRA PROHIBITIONS ALIGN WITH ITS STATED PRINCIPLES?

The post-2012 amended *AHRA* continues to offer as main solutions to regulating ARTs in Canada: prohibiting certain uses of ART (the ones listed on pages 2-3 above, which include research resulting in the "genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants"), and banning payment to donors and surrogates (although we have seen above that there is evidence that the latter solution has not been enforced). We now analyze whether these solutions, as enacted by *AHRA*, satisfy the law's stated guiding principles.

Research involving germline genetic modification

If the activities the *Act* prohibits are not limited to those aiming to result in a pregnancy, but also include basic research activities, then we should ask which of the stated *AHRA* principles such prohibition corresponds to. Clearly, banning research that "alters the genome of a cell of an in vitro embryo such that the alteration is *capable* of being transmitted to descendants", without ever planning on implanting the embryo in utero, has no bearing on "health and well-being of children born through" ARTs or on discrimination. While fears of negligent or even rogue implantation are reasonable, they can be prevented by clearly separating the locations where research is conducted from fertility clinics.

The *AHRA* principles of free and informed consent, protecting women as more directly affected by ARTs and preventing exploitation of people for commercial ends, can be seen as being relevant, since ART research without aiming to implant requires the donation of gametes or embryos for research. The requirement of informed consent can be easily respected by obtaining it from progenitors of the embryo or the donors of the gametes for this type of research. Since obtaining eggs is riskier and more burdensome than obtaining sperm, donation for research arguably affects women's health more than men's and could result in exploitation. However, we, as a society, accept egg donation, provided informed consent has been obtained, for uses not prohibited by *AHRA*. Arguably, women should be allowed to autonomously decide which uses they wish to donate their eggs for.

The principle of protecting human individuality and diversity, and the integrity of the human genome, could theoretically be used to argue in favor of banning research activities that alter the germ-line. However, such arguments are far from obvious and need to be spelled out. This would require social debate on what the "integrity of the human genome" means. It may turn out that Canadian society believes the integrity of the genome to be better protected by editing certain genetic mutations out. Similarly, the principle of protecting and promoting human health, safety, dignity and rights in the use of ART and related research can be seen as aligned with allowing research affecting the germ-line, since doing so would explicitly aim at promoting human health, safety, dignity and rights. Indeed, the only way research with embryos aiming to eradicate severe diseases can be an affront to dignity is if embryos are afforded more right to dignity than humans after birth[3]. Banning research activities thus arguably goes against the spirit in which the law was enacted.

Paying donors and surrogates

While the *Act* purports to be motivated by concern over the exploitation of children, women and men for commercial ends, the fact that it only bans payment to donors and surrogates, but allows profit by for-profit fertility clinics, may arguably raise concerns. Granted, Anne McLellan, specifically singled out "people" as those who should not profit: "Canadians do not want *people* to

[3] As was supported, for example, by M.P. Rob Merrifield.

engage in activities that create human life for profit" and "We will not let *people* profit from the creation of a baby", possibly in contrast with entities (arguably composed of people) who *were* allowed by the *Act* to create human life for profit. Paul Szabo noted this inconsistency between the principle and the law:

> Obviously it is contemplated that there would be commercialization, money changing hands and big business after the donation is made, but the bill specifically prohibits any exchange of money between the donor and any other party. Why is that? Maybe the member could give us an idea of why it is that the donors have to sign off to say that they would not benefit from making their donation whereas others can make money.

Pat Martin, in turn, was more explicit in his condemnation of the bill: "Bill C-56 seems to be geared to favour the biotechnology industry". The ban on paying third-party participants in ART, especially in the absence of regulations and clear guidance regarding what compensation is allowed, promotes a grey market and puts donors and surrogates in a constant state of fear of violating the law. It has been demonstrated that this reality harms them further by making them avoid seeking medical attention when required. A ban on payment therefore not only singles them out as the parties not allowed to profit, but also increases the possibility of other harms. Within the confines of the current unquestioned 'consensus' that fertility clinics ought to be left to so-called 'laissez-faire' market forces, it is only reasonable to demand that at least those who can be most taken advantage of – donors and surrogates – would be appropriately compensated.

CONCLUDING RECOMMENDATIONS

Two recommendations for updating *AHRA* are of relative urgency:

1. Allow payment to donors and surrogates, at least as long as payment to other stakeholders is permitted. Draft regulations aiming to minimize financial exploitation of donors and surrogates.
2. Allow pre-clinical research, with no intent of pregnancy, involving germline genetic modifications.

The first recommendation should have been part of the *Act* from the beginning, if the guiding principles outlined in the law were taken seriously, as was pointed out by certain MPs during the parliamentary debate, and is currently proposed in a bill that was tabled in 2018 (Housefather, 2018; Macleod, 2018). As outlined above, the second recommendation is more in line with the *Act*'s guiding principles than its converse. More long-term research on Canadians' views regarding various uses of ART is needed to regulate ART accordingly.

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