Pamela M. White, "Canada's regulation of assisted reproduction: morally coherent and evidence-based?" Doctor of Philosophy (PhD) By Publication, University of Kent

ABSTRACT

My published body of work submitted for PhD by Publication explores legal, ethical and health policy implications for surrogates, gamete donors, and patients of Canada's morally incoherent and misshapen approach to assisted human reproduction governance. Modelled on a legislative framework similar to that of the U.K. Human Embryology and Fertility Act, 1990 (amended 2008), the passing of Canada's Assisted Human Reproduction Act 2004 was met by relief by policy makers pleased to have finally found a workable compromise. However, it was a deeply flawed law. As soon as the Act was passed, Quebec launched a constitutional challenge, which resulted in the 2010 Supreme Court of Canada decision (*Ref re AHR*) rendering *ultra vires* the sections of the Act that sought to use federal criminal code powers to regulate in areas of provincial constitutional jurisdiction, notably the practice of medicine and research. Subsequently, Canada's assisted human reproduction landscape has dissolved into a laissez-faire professionally managed activity. What remains of the federal Act is a set of prohibitions criminalising payment of surrogates and gamete donors, use of an unscreened and untested ovum obtained from a traditional surrogate and used in her own surrogate pregnancy, sex selection, and genomic alterations. By 2019, the reimbursement regime for surrogates and gamete donors' expenses and the screening and testing criteria of human ova had yet to be regulated by the federal government.

It is against this misshapen and morally incoherent legal backdrop that my work uses case studies, empirical interview findings and statistical data analysis of birth and assisted reproduction registries to expose unethical fertility treatment practices provided to surrogates. I uncover and examine regulatory gaps; for example, when surrogates are both ova donors and traditional surrogates. I investigate emerging trends in the off-shoring of international surrogacy to Canada and I explore

implications for those making embryo disposition decisions when confronted by annual cryopreservation storage renewal contracts.

As a body of work my publications have pushed the boundaries of what we know and it has revealed important gaps in knowledge (what we do not know) about surrogacy and fertility treatments in Canada. My papers bring together for the first time a range of data sources, including empirical interviews with IVF patients and descriptive and quantitative analysis of treatment data and birth registration information to make a significant and innovative methodological contribution to feminist legal studies and our understanding of liminal regulatory spaces. Where possible, I strive to give voice to the experiences of women and men undergoing fertility treatment. My published output also contributes to an improved and clearer understanding of the ideological structures underlying reproductive health information collection systems. This landscape reveals a number of thorny dilemmas arising from founding fertility law and regulation on misleading and inappropriate information.

Each paper seeks to make an independent original contribution to the literature; but together as a body of work, the emergent picture is as follows:

- Canada's approach of delegating assisted reproductive practices to a laissez-faire soft-governance regulatory system is a risky business with potential harms for patients, including donors and surrogates. Failure to track outcomes and a lack of monitoring of adherence to guidelines drives home the need to shape law and policy on sound information and empirical findings that give voice to the lives lived within the confines of law. To redress this, we need better data to foster evidence-based decision making. Efforts thus need to made at the provincial and federal levels to develop a transparent and accessible assisted reproduction registry compliant with WHO standards. Qualitative research with surrogates, intended parents and other actors in the fertility treatment industry needs to be undertaken. A donor registry should be established.

- From a legal perspective, my work calls for more robust and better tailored regulation. This should involve decriminalisation of financial compensation provided to surrogates and gamete donors; the development of policies to discourage, if not ban non-resident intended parents; provincial regulation of the practice of fertility medicine; and a standardised approach to parentageship across all provincial jurisdictions.

The published works I am submitting:

1. Chapter 10: 'A Less Than Perfect Law': The Unfulfilled Promise of Canada's Assisted Human Reproduction Act' (2015) in Kirsty Horsey (ed.) *Revisiting the Regulation of Human Fertilisation and Embryology*. London: Routledge 170-184.

2. 'Moral Evils v. Health and Safety Evils: The Case of an Ovum 'Obtained' From a 'Donor' and Used By the 'Donor' in Her Own Surrogate Pregnancy' (2018) 31(2) *Canadian Journal of Family Law* 55-126.

3. 'Life on the Liminal Bridge Spanning Fertility and Infertility: A Time to Dream and a Time to Decide' (2017) 24 *Journal of Law and Medicine* 886-899.

4. 'Hidden from View: Canadian Gestational Surrogacy Practices and Outcomes, 2001-2012' (2016) 24 *Reproductive Health Matters* 205-217.

5. 'One for Sorrow, Two for Joy': American Embryo Transfer Guideline Recommendations, Practices, and Outcomes for Gestational Surrogate Patients (2017) 34 *Journal of Assisted Reproduction and Genetics* 432-443.

6. 'Commercialization, Altruism, Clinical Practice: What Explains Similarities and Differences in Californian and Canadian Gestational Surrogacy Outcomes' (2018) 28 *Women's Health Issues* 239-250.

7. Chapter 2: ''Why We Don't Know What We Don't Know" About Canada's Surrogacy Practices and Outcomes in V. Gruben, A. Cattapan & A. Cameron (eds.*) Surrogacy in Canada: Critical Perspectives in Law and Policy.* (2018), Toronto: Irwin Law 51-80.

8. ‘Canada’s Surrogacy Landscape is Changing: Should Canadians Care?’ (2017) 39 *Journal of Obstetrics and Gynaecology Canada* 1046-1048.

9. Chapter 7: ‘Desperately Seeking Surrogates: Thoughts on Canada’s Emergence as an International Surrogacy Destination’ in V. Gruben, A. Cattapan & A. Cameron (eds.*) Surrogacy in Canada: Critical Perspectives in Law and Policy.* (2018), Toronto: Irwin Law 213-243. [Co-authored with Karen Busby. Each author contributed 50%. [See Annex A].

Annex A: PhD Documentation

1. Ethics Review Statement and Consent Forms for Eggs and Embryos for Research Project.
2. Co-author statement from Dr. Karen Busby.
3. Kent Law School Ethics Review.

CANADA'S REGULATION OF ASSISTED REPRODUCTION: MORALLY COHERENT AND EVIDENCE-BASED?

A. INTRODUCTION

In my published work submitted here, Canada's laissez-faire approach to assisted human reproductive governance provides a springboard to the investigation of specific topics. Taken together, these articles create a picture of Canada's misshapen and morally incoherent assisted reproductive landscape. Each published paper is a stand-alone article. Yet, four overarching themes emerge from the findings of the nine submitted papers:

i) non-compliance with professional guidelines and a lack of population health information contributes to treatment harms for fertility patients, including surrogates and egg donors;
ii) normative notions of 'fertility and infertility', 'the donor' and 'the patient' influence decision-making, counselling and guidelines, especially when third-party fertility treatments are involved;
iii) managed ignorance in the establishment of what we know and do not know about assisted reproduction practices and outcomes shapes assisted reproduction registries and data collection systems and contributes to poor policy and law; and
iv) challenges for governance when the practice of medicine is a provincial responsibility but criminal code sanctions are federal responsibilities and the practice of fertility medicine is mobile and difficult to contain within national boundaries.

My published work does not purport to provide a comprehensive recommended solution for Canada's problematic assisted reproduction governance challenges. In a country where the practice of medicine is a provincial constitutional responsibility,

the federal government is left with few options. It has continued to criminalise activities viewed as constituting moral or health evils, such as commercialisation of surrogacy and gamete donation, sex-selection, cloning and genome alteration. It has done little to encourage a pan-Canadian approach to parentage in cases where assisted reproductive techniques have been used. Nor have the provinces sought to regulate fertility medicine; preferring instead to leave this responsibly to provincial professional associations to manage.[1]

My work offers legal and social policy investigations of harms that can occur for patients and to those conceived as a result of assisted reproduction techniques when governance is decentralised and left to non-governmental bodies such as professional associations. As a body of work, my publications make a number of recommendations for law and policy regarding better data collection and adoption of World Health Organization (WHO) standards for Canada's assisted reproduction registry. I call for the establishment of accountability standards. I also join the call for provinces to work together to standardise parentage laws and harmonise the regulation of fertility medicine.

[1]Ontario. All Families Are Equal Act (Parentage and Related Registrations Statute Law Amendment), SO 2016, c 23 requires that parties obtain independent legal advice before entering into a surrogacy agreement. Both Ontario and Quebec have placed limits on the number of embryos that should be transferred. In 2016, the Ontario Fertility Program funding IVF established that one embryo was to be transferred per funded cycle. See online: www.ontario.ca/page/get-fertility-treatments. In Quebec, see An Act Respecting Clinical and Research Activities Relating to Assisted Procreation, CQLR c A-5.01, s 10.3, which states: "In the course of an *in vitro* fertilization activity, only one embryo may be transferred into a woman. However, in taking account the quality of embryos, a physician may decide to transfer two embryos if the woman is 37 years of age or over. This requirement was first put in place in 2015 by Bill 20, SQ 2015, c 25, s 3.

Historical Overview of Canada's Assisted Human Reproduction Act 2004

To understand Canada's assisted human reproduction legislative landscape and the harms that I reveal in my work, it is important to chronicle briefly the history of Canada's Assisted Human Reproduction Act 2004 (AHR Act),[2] discuss the legacy of 2010 Supreme Court of Canada (SCC) decision (*Ref re AHR*), identify the 2012 legislative amendments that I write about in my work, and comment on the 2016-2019 regulatory AHR Act consultations.[3]

In formulating its 2004 assisted reproduction legislation, Canada sought to avoid a U.S. model of private market fertility medicine[4] by adopting a federal criminal code-based regulatory and governance system stylised on the U.K. Human Fertilisation and Embryology Act (HFE Act) 1990 (amended 2008). The AHR Act 2004 intended to regulate the practice and licence IVF clinics. It permitted the use of human gametes and embryos in assisted reproduction and the altruistic donation of gametes

[2] Assisted Human Reproduction Act 2004 c.4.

[3] Health Canada, News Release, "Government of Canada plans to introduce regulations to support the Assisted Human Reproduction Act" (30 September 2016), online: <www.canada.ca/en/health-canada/news/2016/09/governmentcanada-plans-introduce-regulations-support-assisted-humanreproduction-act.html>; Canada Gazette, Government Notice, 150:40, "Assisted Human Reproduction Act" (1 October 2016), online: www.gazette.gc.ca/rp-pr/pl/2016/2016-10-01/html/notice-aviseng.html#ne l; Canada Gazette, Proposed Regulations, *152:43,* "Safety of Sperm and Ova Regulations" at 3637-734; Canada Gazette, Proposed Regulations, *152:43,* "Reimbursement Related to Assisted Human Reproduction Regulations" at *3735-40;* Canada Gazette, Proposed Regulations, *152:43,* "Regulations on the Administration and Enforcement of the Assisted Human Reproduction Act" at 3741-44; Canada Gazette, Proposed Regulations, 152:43, "Regulations Amending the Assisted Human Reproduction (Section 8 Consent) Regulations" at 3745-51, online: <www.gazette.gc.ca/rppr/pl/2018/2018-10-27/html/index-eng.html>; Health Canada, Draft Directive: Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donor*s,* Ottawa: Health Canada, 2018, online: www.canada.ca/en/health-Canada/programs/consultationassisted-human-reproduction-regulations/technical-directive.html#c.

[4] David Snow, "Criminalizing Commercial Surrogacy in Canada and Australia: The Political Construction of 'National Consensus'" (2016) 51 *Australian Journal of Political Science* 1 at 4.

and embryos and surrogacy only when undertaken pursuant to regulation. The Act criminalised activities considered to represent moral and health evils such as commercial surrogacy and gamete donation, human cloning, genetic germ line alteration, embryonic sex selection, and the use of untested and unscreened third-party human gametes.

Where the Act differed in a fundamental way from its U.K. counterpart was that Parliament embedded a series of ethical principles into the legislation. This approach is not customary in criminal law[5] though other Commonwealth nations have adopted a similar tactic.[6] Canadian lawmakers intended that a framework of broad-based ethical principles of beneficence, social justice (equality), consent, and altruism would underpin the practice of assisted reproduction in Canada. [7] These ethical principles have remained within the Act notwithstanding the 2010 SCC decision, *Ref re AHR,* and the 2012 amendments made to the Act. My work returns time and again to the unfulfilled promise of these ethical principles.

I argue that the prominence given by Parliament to the specification of a set of ethical principles could have represented a fundamentally more ambitious and ultimately more enduring project than the Act's identification of prohibited and permitted activities. For example, the statutory focus on autonomy as specified in s.3(a)

[5] Glen G. Mitchell, 'Not a General regulatory Power – A Comment on reference re Assisted Human Reproduction Act' (2011) 54 Supreme Court Law Review 633 at 637.
[6] New Zealand. Assisted Human Reproduction Technology Act 2004 No. 92, section 4: Principles; Australian State of Victoria Assisted Reproductive Treatment Act 2008 No. 76. At section 5: Guiding Principles. See also, Benjamin Atkin. "Regulation of assisted Human Reproduction: The Recent New Zealand Model in Comparison with Other Systems"2004. Vol.11 *RJP/NZACL Yearbook* 81-100.
[7] Mitchell (n5) 638.

embeds the pillar of free and informed consent into the Act. In regulation (Section 8: Consent), permission regarding the use and donation of human reproductive materials is a foundational right of the patient. Yet, the amendments made in 2012 to s.10(2)(c) of the Act can create regulatory confusion whereby traditional surrogates using IVF risk falling into a 'betwixt and between' liminal decisional bounded space. Another ethical principle at s.3(d) mandates non-discrimination in access to assisted reproduction treatments. This equality principle signals the importance of social justice for all patients, regardless of marital status, gender or orientation; a condition that applies to all patients, including non-Canadian resident intended parents. However, the sweeping decision of the SCC in *Ref re AHR* to render all sections of the AHR Act dealing with regulation of health implications of assisted reproduction *ultra vires* leaves the ethical principles of beneficence in a legal liminal state in that they are largely unenforceable statements of good intentions. This situation is most apparent in the areas of population health surveillance, donor registry, and consumer protection as the SCC considered these activities when undertaken by the federal government to be constitutionally invalid.

The fatal flaw of Canada's AHR Act was the grafting of a governance system adopted from the U.K. HFE Act 1990 (amended 2008) onto a jurisdiction where provinces and not the federal government are responsible for the delivery of medicine. Regrettably, the Act's heavy-handed use of federal powers fed the flames of provincial acrimony and set in motion a swift and unwavering legal response on the part of the provinces determined to oppose and staunch federal encroachment into

areas of provincial constitutional responsibility.[8] In 2010, the SCC sided with Quebec in its divided decision (4:4:1) *Ref re AHR* which carefully considered and weighed the pith and substance of the Act. The Court concluded that the licencing of IVF clinics and governance of fertility medicine were areas that properly fell within provincial constitutional jurisdiction. Canada's senior court thus rendered the sections of Act regulating fertility medicine *ultra vires*.[9] The SCC also removed federal jurisdiction over measures established as beneficent protections for women and children, such as the Personal Health Information Registry, Donor Registry and the Agency responsible for oversight and regulation.[10]

The implications for law and policy of these elements of the SCC decision shape my published work and inform my efforts to assess risks created by reliance on soft governance and provincial failure to legislate. I examine harms for patients of not having a reliable and transparent assisted reproduction registry and I explore frustrations for law, regulation and policy of being tasked to develop social protections in a knowledge vacuum. It is ironic to note that Canada, by seeking to avoid an American style of fertility medicine, lacks the consumer protections that the 1992 U.S. federal Act achieved.[11] Another irony is that, depending on the U.S. state,

[8]Décret 1177-2004; Décret 73-2006; *Attorney General of Quebec v Attorney General of Canada*, 2008 QCCA 1167, [2008]. RJQ 1551, 298 DLR (4th) 712.
[9] 2010 SCC 61 [2010] 3 S.C.R. 457. Sections rendered ultra vires: s. 10, 11, 13-18; ss 40(2) (3), (3.1), (4) and (5) and ss. 44(2) and (3).
[10] AHR Act s.10, 13-18.
[11] 106 Stat. 3146 – Fertility Clinic Success Rate and Certification Act of 1992

American surrogates are offered greater health protections than are Canadian-based surrogates.[12]

To complete the brief legislative history, in 2012 the Act was amended to reflect the *Ref re AHR* decision.[13] Health Canada was given administrative responsibility for the Act including regulation and oversight of testing and screening of human gametes used in human reproduction, reimbursement of donors and surrogates, and enforcement of prohibited activities.[14] It was not until October 2016, that Health Canada commenced a consultative initiative designed to address the Act's regulatory deficit.[15] In November 2018, Draft Regulations were published with consultation extending into March 2019.[16] Final Regulations are expected to be placed before Parliament for approval later in 2019.

Federal reluctance to regulate combined with a continued reticence by provincial authorities to intervene alongside the rise of the unelected notably the heightened role

[12] Richard F Storrow, 'Surrogacy: American Style' in Paula Gerber and Katie O'Byrne (eds), *Surrogacy, Law and Human Rights* (Routledge 2016) 193.
[13] Readers are invited to read Paper 1 to gain a fuller picture.
[14] Jobs, Growth and Long-term Prosperity Act, SC 2012, c-19, s.714.
[15] Health Canada, News Release, "Government of Canada plans to introduce regulations to support the Assisted Human Reproduction Act" (30 Sept 2016), online: < https://www.canada.ca/en/health-canada/news/2016/09/government-canada-plans-introduce-regulations-support-assisted-human-reproduction-act.html>; Canada Gazette, Government Notice, 150:40, "Assisted Human Reproduction Act" (1 Oct 2016), online: < http://www.gazette.gc.ca/rp-pr/p1/2016/2016-10-01/html/notice-avis-eng.html#ne1>.
[16] Canada Gazette, Part 1, Volume 152, Number 43. http://www.gazette.gc.ca/rp-pr/p1/2018/2018-10-27/html/index-eng.html; Draft Directives are found at: https://www.canada.ca/en/health-canada/programs/consultation-assisted-human-reproduction-regulations/technical-directive.html#c.

of assisted reproduction societies and the Canadian Standards Association[17] in guideline setting, has created a worrisome Canadian assisted reproductive landscape.

I argue that the 2012 legislative changes and proposed regulations have served to make the Act more misshapen and misguided, not less. Canadian constitutional realities, government inaction, easy access to cross-border reproduction, and growing demand for assisted reproduction treatments has rendered Canada's AHR Act a battered and bruised legislative instrument. My work looks at the harms that regulatory inaction can bring to vulnerable groups. I use a number of different methodologies to achieve a critical analysis of the implications of Canada's misguided and morally incoherent assisted reproductive Act.

B. SUMMARY OF SUBMITTED PAPERS

This section provides a brief summary of the nine papers submitted for PhD by Publication. The listing of the papers reflects the themes that will be discussed at greater length in Parts C and D of this overview document.

B.1 The genesis of Canada's morally incoherent assisted reproductive law

Paper 1, entitled *'A Less Than Perfect Law',* chronicles the development of assisted human reproductive law and regulation in Canada. Unlike other scholarly work discussing the AHR Act[18], my paper examines the ethical principles cited in the Act

[17] Canadian Standards Association was contracted by Health Canada to establish assisted reproduction guidelines in the absence of regulation. See: Standards Council of Canada, CAN/CSA-Z900-17 Tissues for Assisted Reproduction, (2017: Standards Council of Canada).
[18] Assisted Human Reproduction Act 2004, c.4.

and maps them against Canada's reproductive regulatory and governance regime. The paper examines the impact of the SCC decision in *Ref re AHR*[19] and expands on the policy frameworks that have influenced legislative change since the 2010 SCC decision. The paper is an important building block and forms the foundation for the remaining eight papers for it reminds us of Parliament's intentions to embed ethical principles of non-maleficence, autonomy, equality and non-discrimination into the practice and governance of assistance reproduction in Canada.[20] It underscores that federal law in the area of health, which is a provincial constitutional matter, is restricted and confined to the control of moral and health evils: the pith and substance of the Act.

B.2 Liminal regulatory spaces

Paper 2, *'Moral Evil v Health Evil',* focuses on changes made to section 10(1) of the Act. In this amendment, the federal government seeks to reduce harm to human health and safety arising from use of human sperm or ova, including the risk of disease transmission. The legislation now mandates screening and testing of "obtained" ovum "donated" by a "donor" and used in her own surrogate pregnancy. The paper argues that this change creates a dangerous liminal regulatory space; one that transforms the surrogate into a third-party donor even though she incurs no health and safety risk to herself as she is the recipient of her own ova embryo. Screening for genetic implications that could have health consequences for the surrogate-born child makes a stronger case in support of mandatory testing, however

[19] 2010 SCC 61 [2010] 3 SCR 457.
[20] AHR Act s.3.

the amendment imposes no similar screening and testing regime on the usual category of traditional surrogates: women who bear genetically-related children conceived through artificial insemination (IUI) rather than IVF. The paper questions the application of federal criminal code powers to control what I conclude is a non-existent health and safety evil. It argues that the actual evil is a moral one whereby criminal code sanctions are being employed to discourage traditional surrogacy when practiced as a result of assisted reproduction techniques.

Picking up on a different kind of harm experienced by those who negotiate Canada's complex regulatory landscape, Paper 3, *'Liminal Bridge'* examines embryo cryopreservation, a technique frequently viewed as providing IVF patients with a reassuring fertility insurance benefit. However, as the paper argues, this characterization fails to encompass the field of dreams that frozen embryo storage and retention create for many infertile couples and individuals. The article uses qualitative interview data from 45 Canadian fertility treatment patients, the majority of whom were interviewed by the author in 2013-14, to explore how liminal spatial and temporal reproductive boundaries were negotiated by patients as they made decisions about their stored embryos. It sheds light on the investments made by patients in "hope technologies", examines the destabilisation and category mixing that fertility preservation can generate, and investigates the liminal places in which patients and their stored embryos dwell and experience time. Canada imposes no embryo storage retention time limits. This article argues that to do so would confuse notions of embryo storage time with that of reproductive purpose which could lead to

further ambiguity and liminality. It contributes to the existing literature on the topic by examining how annual private-sector storage renewal contracts, Canada's Section 8 (Consent) Regulations,[21] and liminal notions of (in)fertility challenge patients' abilities to make storage, use and disposition decisions.

B.3 'Why we don't know what we don't know': Implications of soft governance

Paper 4, '*Hidden from View'*, brings together for the first time a synthesis of information about surrogacy in Canada. This paper raises some troubling questions about the fertility treatments provided to Canadian gestational surrogates. Using information that I obtained from Canada's Assisted Reproduction Registry (CARTR Plus), it traces the growing incidence of multiple births experienced by Canadian gestational surrogates over the period 2003 to 2012. Among the findings, the paper shows that by 2012, one-quarter of gestational surrogates received a single embryo transfer compared to almost one-half of other IVF patients. This is a worrisome situation given the known health implications of multi-fetal pregnancies. The paper recommends that greater attention needs to be paid to counselling provided to gestational surrogates and that review of the 2007 Canadian Medical Association[22] surrogate treatment guidelines is warranted. Finally, the paper describes the difficulties in obtaining accurate data about Canadian assisted reproductive medicine practices. Without public access to information, it is difficult to identify potentially harmful practices.

[21] Section 8 (Consent) Regulations SOR/2007-137.
[22] Daniel R. Reilly, 'Surrogate pregnancy: A guide for Canadian prenatal health care providers' (2007) 176 (4) Canadian Medical Association Journal 483.

'*One for Sorrow, Two for Joy*' (Paper 5) profiles the case of Melissa Cook, a California gestational surrogate experiencing a multiple-birth pregnancy following the IVF transfer of three embryos comprised of donor eggs and sperm provided by the intended father, to explore troubling issues about fertility treatment practices involving gestational surrogates, twin preference and third-party reproduction medical decision-making. It focuses on multiple-embryo transfers and offers an original analysis of data I obtained from the U.S. national-assisted reproduction registry maintained by U.S. Centers for Disease Control and Prevention (CDC). It undertakes a review of American Society for Reproductive Medicine–Society for Assisted Reproductive Technology (ASRM-SART) embryo transfer guidelines (1998-2016). It examines single and multiple-embryo transfer trends over a 12-year period (2003 to 2014) and compares results to the recommended guidelines. Findings reveal that guidelines were followed in fewer than four out of ten embryo transfers. The paper argues that ensuring equitable medical treatment for all recipients of IVF requires the adoption of treatment guidelines tailored to and offering protections for specific patient groups. Once in place, guidelines must be robustly implemented. The paper lays the ground-work for study examining adherence to Canadian embryo transfer guidelines, a set of soft-governance practices modeled on the U.S. approach.

Paper 6, '*Commercialization, Altruism, and Clinical Practice*' documents the increase in surrogate births occurring in California and Canada. It details how, over the five (5) years from 2010 to 2014, the number of babies born to gestational

surrogates having IVF treatment in California doubled. In Canada, it grew by over a third. Adherence to voluntary ASRM-SART and Canadian Fertility and Andrology Society (CFAS) embryo transfer guidelines was modelled. The paper found that embryo transfer guideline adherence over the period was 42% in California and 48% in Canada. The paper concludes that, regardless of where on the commercial/noncommercial boundary North American surrogates reside, they are more likely to receive more donor ova embryos per IVF transfer than other patients. The paper suggests that the altruistic desire to assist childless couples and individuals create families, along with clinic practices encouraging multiple embryo transfers, appear to play major roles in treatment decision-making. The paper recommends more research into third-party reproduction consenting mechanisms.

'*Why We Don't Know*' (Paper 7) traces my journey to uncover what we know and do not know about surrogacy and fertility medicine practices and outcomes in Canada. Over the past several years I have searched broadly and tirelessly to find data on assisted reproduction practices and outcomes. In this paper, I explore a number of reasons that may explain this difficult situation. Specifically, it asks: 'Why don't we know what we don't know?' I query why is has been so difficult to obtain reliable and consistent information about assisted reproduction and the practice of surrogacy. I seek to understand whether there is something unique about fertility medicine — and, in particular, surrogacy — that belies rigorous measurement and information-based decision making. In attempting to answer these questions, I examine how the strategic management of information shapes what we know and don't know about

surrogacy. I look at how IVF clinic practices influence decisions about the data that are collected. I assess the implications of not knowing about fertility outcomes for patients, policy, and law. I recommend that there needs be an opportunity for surrogates, children, intended parents, counsellors, and clinicians to provide input into research and data collection frameworks. I advise that discussions about remaking Canada's surrogacy law and regulations must give priority to consideration of assisted reproduction information systems including determination of who gets to set what we know and how we know about assisted reproduction patients, including surrogates.

B.4 Borderless fertility medicine: Implications for Canadian law, policy and patients

It appears, based on my findings, that the number of 'surrogacy tourists' choosing Canada as their destination for treatment is growing rapidly. Paper 8, '*Canada's Surrogacy Landscape is Chang*ing' provides a commentary on the growth of surrogacy in Canada, notably the increase in non-Canadian resident intended parents. It shows that over a third of surrogate babies were born to non-Canadian residents, a pattern mimicking that of California, a jurisdiction privileging paid surrogacy. The paper asks a number of questions about legal and policy problems that this trend may create for Canada. It recommends that more attention be paid to this emergent phenomenon.

Finally, Paper 9, '*Desperately Seeking Surrogates'* is a legal and social policy response to the questions asked in Paper 8. It is my sole co-authored paper (with Dr. Karen Busby). It explores why Canada is emerging as an international surrogacy destination and asks whether Canadians should be concerned about this development. Returning to focus explicitly on the ethical principles considered at the outset of my work, it examines whether concerns about consent, distributive justice, exploitation, and commodification raised about reproductive medicine practices in the Global South apply now that Canada has emerged as a site attracting international fertility patients. It then explores whether there are other reasons for Canadians to feel uneasy about international intended parents seeking surrogates in Canada, which leads into a discussion on whether Canada should introduce residency restrictions on surrogacy. It closes by noting research gaps and suggests that Canadian lawmakers consider prohibiting international surrogacy in Canada or, at least, level the playing field between international and local intended parents by permitting surrogates to be compensated by Canadian intended parents.

With a brief summary of each paper having been provided, the next section of this overview document will elaborate on the methods employed and expound on the theoretical concepts used in the papers. Major contributions to the area of medical ethics and legal studies will be discussed and key findings along with recommendations will be presented in subsequent sections.

C. RESEARCH METHODLOGIES

This section of the Overview document aims to provide an explanation of and a detailed focus on the more innovative methodologies in evidence in my published peer-reviewed work. This section can be divided in to two sub-sections: 1) Quantitative analysis of assisted reproduction registry information; and 2) Qualitative interview analysis.

C.1 Quantitative analysis of assisted human reproduction registries

As has been discussed, one consequence of the SCC decision *Ref re AHR* was the removal of federal jurisdiction over collection of population health information pertaining to fertility treatments and outcomes for patients. Canadian IVF Directors and the CFAS manage Canada's sole registry on assisted reproduction: CARTR Plus. The provinces of Ontario and British Columbia have recognized parentage related to assisted reproduction births and hold data on births to surrogates.

In my work, I have accessed and analysed these sources of Canadian information as well as U.S. assisted reproduction information collected by the CDC and held in their national assisted reproduction registry, National Assisted Reproductive Technology Surveillance System (NASS). I requested tabular data for the periods 2001-2014 pertaining to embryo transfer cycles for surrogates and non-surrogates. I undertook descriptive cohort and trend analysis. I compared statistical risks of multiple embryo transfers using accepted methods (risk ratio analysis). The details of these analyses are explained in my publications (Papers 4 - 8).

My use of assisted reproduction registry data and vital statistics birth registrations signals an innovative approach in the field of feminist legal studies in that my published work examines not only the outcomes of fertility medicine but also how treatment knowledge is managed and developed by soft-governance bodies. In my work, I have extended theoretical thinking advanced by Proctor[23] and Schiebinger[24] regarding the management of ignorance. Using my extensive knowledge of data development techniques, I examine the structure of these data repositories.[25] I argue in Paper 7 that assisted reproduction registries do not employ a 'neutral' classification system or use a patient-centered framework. In Canada and the U.S., such registries reflect technologies of medicalisation and bio-power.[26] The manner in which treatment data are structured normalises patient/doctor relations, privileges treatment options, defines and shape the characteristics of reproductive bodies.[27]

For example, it is convenient for fertility clinics to organize patient encounters by IVF cycle given that procedure billing and medical treatments usually occur on a per–IVF cycle basis. Yet, the term "IVF cycles" means very little to the general

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[23] Robert N Proctor, *Cancer Wars: How Politics Shapes What We Know and Don't Know about Cancer* (Basic Books 1995).
[24] Londa Schiebinger, 'Agnotology and Exotic Abortifacients: The Cultural Production of Ignorance in the Eighteenth-Century Atlantic World' (2005) 149:3 *Proceedings of the American Philosophical Society* 316; See also: Steven Hilgartner, 'Selective Flows of Knowledge in Technoscientific Interaction: Information Control in Genome Research' (2012) 45:2 *British Journal for the History of Science* 267; Jennifer L Croissant, 'Agnotology: Ignorance and Absence or Towards a Sociology of Things That Aren't There' (2014) 28:1 *Social Epistemology* 4.
[25] I worked for over 25 years as a senior official at Statistics Canada developing and analysing demographic and census databases.
[26] Michael Foucault, Power/Knowledge: Selective Interviews and Other Writings 1972-1977. Colin Gordon (ed) (Patheon 1980); Peter Conrad, *The Medicalization of Society: On the Transformation of Human Conditions into Treatable Disorders* (Johns Hopkins University Press 2007).
[27] Alan Hyde, *Bodies of Law*. (1997) (Princeton University Press 1997) at 76-78.

public or the newly initiated IVF patient. Using the IVF cycle as the unit of observation focuses attention on results achieved by embryo rather than on the outcomes for the patient, client, or surrogate. For the embryologist studying success rates and examining differing techniques, the focus is appropriate. However, such a categorization system renders analysis at the level of the patient difficult, as each patient frequently experiences multiple cycles of IVF transfer or ovarian stimulation. Further complicating the analysis for surrogates is that the surrogate is not classified as being the patient. Rather, the term patient is reserved for the intended parent as they are the party with the infertility problems as well as being the fee-paying client.[28]

The consequence of this structuring of knowledge is that the information being collected about surrogate encounters with IVF clinic treatment overwhelmingly concerns the outcome for the intended parent as the data relating to the surrogate lists the embryo transfers, condition of the embryo, its origin (own embryo meaning the intended mother's embryo) and stage of development. In a surrogate IVF cycle, the number of fetal pregnancies and births outcome per transfer will be recorded. But no information is obtained about the surrogate's socio-economic background, parity (number of previous births and pregnancies including surrogate ones) or her pregnancy and birthing experiences. This approach denies the surrogate a role in reproduction. It makes assessment of appropriate treatment for surrogates difficult and renders monitoring of adherence to guidelines extremely challenging to

[28] Kiran M Perkins et al. 'Trends and Outcomes of Gestational Surrogacy in the United States' (2016) 106:2 *Fertility and Sterility* 435.

undertake for surrogates and ova donors as in both instances they are not defined as patients in assisted reproduction registries.

In Canada, there is little opportunity to effect change to fertility treatment data collection systems as there is no population health agency providing oversight or accountability. The collection and organization of fertility health information is a private-medicine endeavor managed and funded by the CFAS and the IVF clinic directors. These parties are not transparent in the publication of assisted reproduction treatment information. Nor are they forthcoming about the management of the registry. My access to the data held in CARTR Plus was approved by the IVF Directors who adjudicate the ethical and scientific value of proposed studies. My applications were all approved apart from the most recent when I was refused access to the data on multiple embryo transfers to same-sex couples. A recent qualitative interview study suggests that same-sex male couples prefer to have a twin surrogate birth.[29] I sought to validate this finding using national data, but was refused the data on surrogate embryo transfers for same-sex intended parents. Without access to this information, it is not possible to monitor trends in twin preference for this group and other types of intended parents.

[29] Sophia Fantus, *The Path to Parenthood isn't Always Straight: A Qualitative Exploration of the Experiences of Gestational Surrogacy for Gay Men in Canada – Perspectives of Gay Fathers and Surrogates.* A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy Factor-Inwentash Faculty of Social Work Joint Centre for Bioethics University of Toronto. 2017.
https://tspace.library.utoronto.ca/bitstream/1807/80680/1/Fantus_Sophia_201711_PhD_thesis.pdf

It is unfortunate that one of the consequences of Canada's desire to avoid what Snow has characterized as the pitfalls of the U.S. private medicine model resulted in Canada closing the door on a consumer protection approach, like the one adopted by the U.S.[30] In 1992, the U.S. passed legislation requiring all IVF clinics to transmit IVF clinic data to the CDC.[31] In retrospect, the American approach, which involves a unique public-private partnership between the CDC and the professional associations of the ASRM-SART might have been a more appropriate registry model for Canada. Indeed, similar arrangements between federal/provincial governments and institutions/ businesses exist in other data collection contexts in Canada including, cancer, vital statistics, education data and policing.[32] Had Canada adopted a similar model, a public health organization such as Statistics Canada or the Canadian Institute for Health Information (CIHI) could have managed the population health elements of an assisted reproduction registry for Canada.[33]

Under this model of data governance, Canada would have had a national data registry founded on data accuracy and transparency. There would also have been an opportunity to update registry elements to better measure changing fertility treatment advancements. It would have also provided needed public information about fertility

[30] Snow (n4) at 4.
[31] 106 Stat. 3146 – Fertility Clinic Success Rate and Certification Act of 1992.
[32] See the Statistics Canada data holdings at www.statcan.gc.ca. The Canadian Cancer Registry (CCR) for example is described as a population-based registry that includes data collected and reported to Statistics Canada by each provincial/territorial cancer registry (PTCR). The person based CCR collects information about each new primary cancer diagnosed among Canadian residents since 1992. The objective is to produce standardized and comparable incidence data that can be used to assist and support health planners and decision-makers to: identify risk factors; plan, monitor and evaluate cancer screening, treatment and control programs; and conduct research at: http://www23.statcan.gc.ca/imdb/p2SV.pl?Function=getSurvey&SDDS=3207.
[33] Canadian Institute for Health Information at: https://www.cihi.ca/en

medicine and provided a measure of consumer protection and awareness. Failure to foresee the consequences of leaving assisted reproduction data governance to the IVF clinics directors must cause us to question the fulfillment of the ethical principle of beneficence specified in the AHR Act. This omission is acutely highlighted by the lack of a donor registry and failure to put limits on the number of children that can conceived using a single third-party donor.

Investigation of the form and function of assisted reproduction registries has influenced me to look at international data collection system protocols overseen by the WHO, notably the International Classification Management of Assisted Reproduction Technology (ICMART).[34] For example, the Canadian registry, CARTR Plus does not collect all of the ICMART required elements. As well, I argue that insufficient examination of the structuring of assisted reproduction registries has occurred with the result that 'what we know and do not know' about the practices and outcomes of fertility medicine has shaped our development of law and policy in unforeseen ways. In this manner, both reproductive knowledge and ignorance are being managed. I suggest that this is an area demanding renewed research focus and application of a patient-centred vision to the collection and management of assisted reproduction data.

[34] For a detailed description of ICMART see Paper 7 at 62-64.

Once I had come to understand how it was that so little information was available about surrogates, I asked the question: What would happen if the paradigm of the assisted reproduction registry was inverted so that the surrogate was classified not as a treatment option but as patient? For example, would it be possible to step outside of the ontology of the fertility clinic concept of treatment success and the science of embryology? If I could accomplish this task, I should be able to shed light on outcomes, best practices, and adherence to soft governance guidelines. In taking this perspective, I chose to investigate whether surrogates received similar fertility treatments and whether there has been an uneven application of recommended treatment guidelines. I expected that this line of enquiry would give recognition to the duty of care and beneficent treatment owed to her.[35]

My attempts to situate the surrogate as the patient relied on the data I was able to obtain on request from the CDC NASS and Canada's CARTR Plus registries. I made requests for data from the CDC over the 2003 to 2015 period.[36] I made similar requests over the same time period for information from the Canada's assisted reproduction technology registry (CARTR Plus) though obtaining data from this source proved to be difficult and administratively onerous.[37] Regarding Canadian birth registration data, I was able to obtain this information using access to information requests made to the British Columbia and Ontario vital statistics

[35] Jason Min and Camille Silvestre, *Guidelines on the Number of Embryos to Transfer* (Canadian Fertility and Andrology Society 2013).
[36] Budgetary restrictions imposed by the Trump administration on the CDC has meant that staff have left the organisation and my most recent data request remains unanswered as the database has not been updated. Email exchanges between CDC and P. White 10 December 2018.
[37] Data requests covered the 2003-2015 period for both Canada and the United States. I requested the same datasets from both CDC and CARTR Plus.

organisations. I obtained ethics review permission from University of Kent Law School for all of the requested data retrievals.

In my work, I have been able to compare surrogate and non-surrogate IVF embryo transfer patterns and model compliance against recommended embryo transfer guidelines. I undertook an exhaustive analysis of the embryo transfer guidelines development process in both jurisdictions (Papers 5 and 6). To assess compliance to the embryo transfer guidelines, I applied the statistical Risk Ratio technique to the data obtained from CDC and Canada's IVF directors.[38] I demonstrated that surrogates have a greater statistical risk than other IVF patients of receiving two or more embryos per transfer. This is a worrisome finding given the known health risks to pregnant women and babies of a multi-fetal pregnancy.[39] Difference in multiple embryo transfer risk is especially pronounced when donor ovum embryos are used, a practice that dominates surrogacy treatments.[40] My findings show that in the United States and Canada, recommended embryo transfer guidelines are more likely to be followed when the patient is not a surrogate and when she uses her own ovum embryos.

[38] Perkins (n28).
[39] MacKay AP, Berg JC, King JC, Duran C and Chang J., 'Pregnancy related mortality among women with multifetal pregnancies' (2006) 107 *Obstetrics and Gynecology*. 563; A. Sazonova et al., 'Neonatal and maternal outcomes comparing women undergoing two in vitro fertilization (IVF) singleton pregnancies and women undergoing one IVF twin pregnancy' (2013) 99 *Fertility and Sterility* 731.
[40] Donor ovum embryos come from a third-party ova donor. Own-use ovum embryos come from the intended mother.

My work causes us to ask a number of difficult questions about the duty of care provided to surrogates. It questions the ability of surrogates to engage in meaningful consent in a multi-party reproductive situation. It reveals the importance and influence on treatment decisions of factors such as twin preference, high fertility treatment costs and the overwhelming desire on the part of all parties to achieve a pregnancy. Yet, information about these considerations is not to be found in existing treatment registries. It is only through in-depth surrogate-focused qualitative research that insights will be gained about the factors influencing treatment decision-making.

To summarize, the use of quantitative statistical techniques is infrequently undertaken in legal studies though this approach is becoming more common in bioethics.[41] My published work in Papers 4 - 7 demonstrate the value of this approach especially when regulatory mechanisms are weak or left to the unelected to establish and monitor. My work also shows the value of multi-national comparisons. I also challenge a number of assumptions about the harms caused by commercial surrogacy. Commercialization of surrogacy has been viewed as an exploitative form of assisted reproduction.[42] My findings support a position that the lack of adherence to guidelines, data systems masking surrogates' encounters with the fertility industry,

[41] Jeremy Sugarman and Daniel P. Sulmasy, *Methods in Medical Ethics*. (Georgetown University Press 2010). See chapter 2: Jeremy Sugarman, Ruth Faden and Alison Boyce, 'A quarter century of empirical research in Biomedical ethics' 21 at 24-25; Chapter 12, Robert A Pearlman and Helene E. Starks, 'Quantitative Surveys' 233.

[42] Alan Wertheimer, *Exploitation* (Princeton University Press 1996) Chapter 4; Julie Shapiro, 'For a Feminist Considering Surrogacy, Is Compensation Really the Key Question?' (2014) 89 *Washington Law Review* 1345; Jenni Millbank, "Rethinking 'Commercial' Surrogacy in Australia" (2015) 12 *Journal of Bioethical Inquiry* 477.

multi-party consenting, and an absence of documentation about surrogate treatments and pregnancy outcomes can reveal potentially exploitative situations. My work illustrates that these potentially exploitative elements operate regardless of the commercial/non-commercial environment in which surrogacy operates. I argue that this area of research and enquiry merits additional theoretical and research attention by feminist legal scholars.

C.2 Qualitative Research Methodology

Paper 3 is founded on a qualitative research methodology. As a Research Associate for the Canadian Institute for Health Research funded project, *Eggs and Embryos for Research,*[43] I was a member of a research team investigating embryo cryopreservation and disposition decisions made by women and men recruited from three Canadian IVF clinics. Research Ethics Board approval for the study, including use of the interview materials in my PhD, was obtained from the IWK Research Ethics Board for the Halifax and Ottawa sites, and from the Montreal Hospital Research Ethics Board for the Montreal site.[44] The Kent Law School Ethics Review permitted the use of the findings in published papers submitted as requirement for a PhD by publication and the Principle Investigator, Dr. François Baylis, of the Eggs and Embryos for Research Project gave me permission to author an independent publication.

[43]Dr. Françoise Baylis was the PI for this project. See Annex for the Ethics Approval for the project.
[44] Canadian Health Research Institute funded Eggs and Embryos for Research Project, 2011-2014 (#EOG-111389). The Kent Law School Ethics Review approval enabled the study of CDC and Canadian assisted reproduction registries, vital statistics birth registration data, and discussions with custodians of these datasets to be undertaken and the results used in peer-reviewed publications.

In this project, I adapted the interview questionnaire that had been developed by Professor Erica Haimes for her U.K. work on Egg Donation and Sharing[45] to create a semi-structured interview survey instrument. As part of the interview team, I conducted interviews and undertook analysis of the transcripts. In the context of my own work (Paper 3), I developed a discursive constant comparison thematic technique that I used to examine interview transcript materials.[46] I took sole responsibility for the analysis, writing and publication preparation of Paper 3. My findings revealed liminal thresholds that patients said they needed to cross as a result of retaining gametes and embryos and making decisions about their use, retention and disposition. The theoretical and legal policy importance of my findings is discussed at greater length in the section of this document dealing with liminal decisional regulatory spaces.

Empirical research is becoming more common among scholars examining law and policy through the eyes of those for whom the legislation is intended to impact.[47] My

[45] Erica Haimes & Ken Taylor, 'Fresh Embryo Donation for Human Embryonic Stem Cell (hESC) Research: The Experiences and Values of IVF Couples Asked to be Embryo Donors' (2009) 24(9) *Human Reproduction* 2142. Dr Haimes was a study member.
[46] Daniel Silverman, *Interpreting Qualitative Data* (SAGE, 4th ed, 2011); Steven Timmermans and Ian Tavory, 'Theory Construction in Qualitative Research: From Grounded Theory to Abductive' (2012) 30(3) *Sociological Theory* 167. See Paper 3 for a description of this technique and an explanation of how it was used.
[47] See for example: Jenni Millbank et al, 'Embryo Donation for Reproductive Use in Australia' (2013) 20 *Journal of Law and Medicine* 789 at 802; Erica Chandler et al, 'Rethinking Consent, Information-Giving and Counselling Concerning Stored Embryos within IVF Treatment' (2013) 20 *Journal of Law and Medicine* 759; Isabel Karpin et al, 'Analysing IVF Participant Understanding of, Involvement on and Control over Storage and Destruction in Australia' (2013) 20 Journal of Law and Medicine 811; Anna Stuhmcke, 'Tick Tock Goes the Clock: Rethinking Policy and Embryo Storage Limits' (2014)

work in Paper 3 draws on hermeneutics, a methodology for dealing with uncertainty.[48] This theoretical approach is especially useful in the examination of liminal states and decision-making.[49] When combined with the tools of qualitative semi-structured interviewing, the approach is a powerful instrument designed to investigate how individuals engage with law and regulation. A central feature of my work is the impact of law and regulation on the health of women and families. The specific twist in the Canadian context is that soft governance mechanisms have replaced regulation, with implications going unnoticed and under-assessed.

I argue in my work that qualitative data analysis allows the researcher privileged understandings. It surfaces new evidence about relationships between gendered harms, legislation and regulatory regimes. The analysis of the implications of Canada's misguided law through the employment of qualitative data methodology brings new insights to feminist legal studies especially about the manner in which law shapes lives and fosters reproductive harm through the imposition of contractual deadlines. The qualitative research methodologies that I employ in Paper 3 supports the analytical work on liminal regulatory spaces advanced by Laurie[50] and developed by Squier[51] in areas of health care. My use of the concept of liminality to understand

22 *Feminist Legal Studies* 285; S Takahasi et al, 'Decision Making Process for the Future of Frozen Embryos by Japanese Infertile Women: A Qualitative Study' (2012) 13 *Medical Ethics* 9.
[48] Diego Gracia, 'Philosophy: Ancient and contemporary approaches' in Jeremy Sugarman and Daniel P. Sulmasy (eds) Methods in Medical Ethics. (Georgetown University Press 2010) 55 at 62-64.
[49] Haimes and Taylor (n45).
[50] Graeme Laurie. 'Liminality and the Limits of Law in Health Research Regulation: What Are We Missing in the Spaces In-Between?' (2017) 25(1) *Medical Law Review* 47.
[51] Susan Merrill Squier. *Liminal Lives: Imaging the Human at the Frontiers of Biomedicine*. (Duke University Press 2004).

the creation and maintenance of liminal legal spaces is discussed in the next section of this overview document.

D. Key Themes

My work explores three key themes flowing from Canada's misguided and incoherent assisted reproduction law and policy: the creation of socially and legally constructed liminal spaces; problems arising from cross-border surrogacy and the manner in which Canadian law and policy enables it to occur; and 'not knowing' – a theme examined in the section on Methodology (C.1) and which I briefly expand on its significance for legal scholars in section D.3.

D. 1: Lives lived in ambiguous liminal legal space: Betwixt and between (in)fertility

Liminality is a construct advanced recently by legal scholars[52], bioethicists[53] and social historians.[54] I use two different reproductive situations to explore and critically assess the concept of liminality and its theoretical usefulness: (i) retention of human embryos; and (ii) traditional surrogacy as defined by s.10(2)(c) of the AHR Act.

[52]Graeme Laurie and Emily Postan. 'Rhetoric or Reality: What is the Legal Status of the Consent From in Health-related research' (2013) 21 (3) *Medical Law Review* 371; Agomoni Ganguli Mitra, Edward S. Dove, Graeme Laurie, and Samuel Taylor-Alexander, 'Reconfiguring social value in health research through the lens of liminality ', (2017) *Bioethic*s, 87.
[53] Helen Allen, 'Experiences of Infertility: Liminality and the Role of the Fertility Clinic' (2007) 14(2) *Nursing Inquiry* 132
[54] Benjamin Thomassen, 'The Uses and Meanings of Liminality' (2009) 2(1) *International Political Anthropology* 5.

Turner[55] pioneered the concept of liminality in the field of cultural anthropology. He used it to examine important life changes and to identify situations where individuals transitioned from one state of belonging to another. He argued that during the process of transition one existed in a betwixt and between state. More recently scholars have come to recognize that the concept of liminality also characterizes transitions occurring between illness and health.[56] Liminality has been applied to processes of migration and settlement, notably to refugees and homeless individuals.[57] In the context of health research, Laurie has applied the concept to the process of obtaining consent from clinical research participants. He argues that consent to clinical research by persons exhibiting the disease for which the treatments are being trialed effects a liminal legal space whereby the consenting process becomes blurred and intermediary as participants exist in a between and betwixt status and transition between patient to research subject statuses.[58]

In my work, I advance the work of Squier who observes that biomedical developments enable the patient to transition from illness and pass into a new and changed health status. I examine how embryo cryopreservation reshapes the form,

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[55] A Van Gennep, *Rites of Passage* (Chicago University Press, 1960); Victor Turner, *The Ritual Process: Structure and Anti-Structure* (Routledge, 1969).
[56] Evelyn Blows et al, 'Liminality as a Framework for Understanding the Experience of Cancer Survivorship: A Literature Review' (2012) 68(10) *Journal of Advanced Nursing* 2155; Lorne Granek and Kenneth Fergus, 'Resistance, Agency and Liminality in Women's Accounts of Symptom Appraisal and Help-Seeking Upon Discovery of a Breast Irregularity' (2012) 75 *Social Science and Medicine* 1753; Samuel Tierney et al, 'Liminality and Transfer to Adult Services: A Qualitative Investigation Involving Young People with Cystic Fibrosis' (2013) 50(3) *International Journal of Nursing Studies* 738. Ronald L Grimes, *Rite Out of Place: Ritual, Media and the Arts* (Oxford University Press, 2006).
[57] Edward W Soja, *Thirdspace: Journeys to Los Angeles and Other Real-and-Imagined Places* (Blackwell, 1996).
[58] Laurie (n50).

extent, and limits of human life course possibilities by enabling a transition from a biological limitation, like infertility, to a state whereby biological constraints become reshaped and redefined by fertility enabling technology.[59]

Liminality as a theoretical construct has been especially useful as it permits legal scholars to identify and examine legal ambiguity. Using the lived experienced of women and men who store frozen embryos, I reveal in Paper 3 how embryo cryopreservation reshapes the limitation of (in)fertility and in so doing creates an unstable and temporary fertility. The need to make decisions about the reproductive use of frozen embryos, continued storage, donation to research, or disposition revealed the destabilizing and shifting grounds produced by fertility medicine. It exposed a liminal bridge between (in)fertility and fertility that patients needed to cross when taking such decisions.

Canada serves as an interesting case example for this type of study. The AHR Act Section 8 (Consent) Regulations are silent on length of storage and destruction of embryos. Yet, the Regulations are prescriptive regarding donation to third parties, use in testing and research, and following the death of a partner.[60] Canadian IVF clinics operationalize storage and consent for use through annual storage payment contracts. In Paper 3, using patient interview data, I document how stored embryos become liminal objects that acquire a transformative legal and instrumental status for those who agree to cryopreserve and retain them. At the same time, Canadian law

[59] Squier (n51) at 17.
[60] Section 8 (Consent) Regulations (n21).

transforms the embryo into a human property object over which the couple and the IVF clinic exercise obligations and rights. For many, the need to renew annual storage contracts provokes a bio-body identity "crisis" triggered by the prospect of (in)fertility and prospect of a loss of reproductive control.

My findings reveal that the absence of direct regulation is not an impediment to decision-making. Patients understood the consequences of failing to pay storage fees and contractual agreement deadlines loomed large, frequently generating confusion and doubt. Canadian patients are not faced with legislated renewal timelines as occurs in the U.K. But the 'flexibility' of the Canadian system comes at a personal cost as annual renewal contract schedules can generate tensions especially as couples share a decisional obligation in law for the use and disposition of embryos. Sharing of decision-making could be problematic and evoked strong views from interviewees, especially when members of the couple disagreed.

Many of those interviewed described their journey between fertility and (in)fertility to be a voyage occurring outside of a support system of the *communitas* of infertile women. Possession of embryos that one did not wish to use, nor donate to childless couples, was a delicate topic especially if one was on a social media chat line with persons searching for embryos. Yet, for some patients, the ability to bring embryos home transformed the sorrow of (in)fertility, doubt and personal indecision into an act of transformation. The act of performing a ceremonial burial facilitated a crossing from one state of being to another, a feature observed by Turner.

My research asks legal scholars to consider law and regulation from the perspective of persons who see their lives shaped and reconfigured by the medicalization of (in)fertility and the governance structures established to regulate fertility treatments. Too often, legal and ethical concerns focus on the moral significance of the embryo, including the ethical implications of its destruction.[61] Most revealing were the findings obtained from women and men who said the destruction of the embryo was not the moral challenge: deciding not to donate them to other couples produced the greater moral dilemma as embryos have a reproductive purpose. Yet, these patients could not envisage another family raising their biological children.

Paper 3 critically examines problems created for patients by imposed deadlines. A regulatory vacuum does not relieve patients of decision-making nor the need to achieve a liminal transition by means of a ritual activity. My findings reveal how decisions made about the stored embryo reframe legal boundaries. I investigated similar constructs when I examine third-party consent and surrogacy. All too often, I found that I was exploring and assessing how regulatory regimes create legal liminal ambiguity. In particular, I found how misshapen law and regulatory mismanagement can generate confusion and harm—the very outcomes that policy, law, and regulation aim to avoid.

[61] See Thomas Douglas and Julian Savulescu 'Destroying unwanted embryos in research. Talking Point on morality and human embryo research' (2009) 10(4) *Science and Society* 307 at 307-8.

Paper 7 explores another form of legal liminal space. I argue that it is through this interpretive lens that one can critically evaluate the 2012 legislative amendment at s.10(2)(c) of the AHR Act and the recent regulatory reform being undertaken by Health Canada.[62] The AHR Act 2004 does not prescribe surrogacy (traditional or gestational) to be a moral evil unless it occurs as a commercialised activity. Yet, the 2012 amendment created another type of criminalised surrogate activity: use by a traditional (genetic) surrogate of her own unscreened and untested ova in her own surrogate pregnancy. Criminalisation is justified on the basis of this practice constituting a health evil.[63] The real "evil," I suggest, is not one of health and safety but a perceived moral one: use by a surrogate of her own 'obtained' ova. The consequence of this twisted notion of a health-based evil is the use of criminal law to restrict traditional surrogate autonomy. When surrogacy employs technology enabling the removal of ova from the body of the traditional surrogate, the frameworks of patient (intended parents), treatment options (surrogacy), and spare part provider (traditional surrogate as ova donor) take precedence. The traditional surrogate and her obtained ova exist in a marginal zone, where consent to use a resultant embryo may become compromised, as occurred in the case of Ms Chonn (Paper 2).

Critical to the creation of a liminal legal space are the conflicting definitions of 'donor' that figure in Canadian statute, regulation and professional guidelines. Paper

[62] AHR Act (as amended 2012) at s. 10 (2)(c).
[63] AHR Act (as amended 2012) at s. 10 (1).

2 unpacks the notion of a 'donor' when applied to a traditional surrogate undergoing IVF. It exposes a lack of legal precision evident in Canadian assisted reproduction legislation, regulation and case law. By tracing possible trajectories evident in the web of rules governing consent, gamete testing and screening, and use by a traditional surrogate of her own ova, the paper reveals dangerous legal liminal gaps. I argue that that overlapping legal status of IVF ova donor and traditional surrogate creates gendered harm and 'bounded objects' amenable to regulatory control. It is the liminal state of being both donor and traditional surrogate that has the potential to create harm as can occur when the traditional surrogate is denied the ability to control the use of her 'obtained' ova. This loss of control occurs when her *ex utero* ova is designated by regulation as a 'third-party' gamete, subject to testing and 'donated' to the intended parents even though it will be used by the surrogate in her own surrogate pregnancy. Once pregnant, the surrogate regains autonomy over her reproduction and her pregnancy.[64] I argue that law and regulation transform the traditional surrogate into a third-party reproductive worker who is both a treatment option (carrier) and spare part provider.[65]

Paper 2 makes an important contribution to the legal liminality literature[66] by revealing the precarious betwixt and between legal positioning of women who engage in IVF traditional surrogacy. Canada's regulatory framework does not adequately recognize the dual status of traditional surrogates who can be egg donors

[64] *R v Morgentaler*, [1988] 1 SCR 30; *Tremblay v Daigle* [1989] 2 S.C.R. 530
[65] Vanessa Gruben, 'Women as Patients, Not as Spare Parts: Examining the Relationship Between the Physician and Women Egg Providers' (2013) 25:2 *Canadian Journal of Woman and the Law*. 249.
[66] Laurie (n50).

should they decide to undergo ovarian stimulation and IVF embryo transfers. Using a feminist legal lens, my work elaborates on the observation made by Laurie[67] that regulation and law can provoke rather than resolve a crisis. This is clear when the contradictory definition of 'donor' in federal and provincial statutes and professional guidelines is crucial to our understanding of the genesis of the acquired liminal status. The gendered harm results from traditional surrogates being transformed and reimagined by law and regulation into a third-party ova donor who poses a 'health and safety' risk. The legal requirement to screen and test her *ex utero* ova creates a potential loss of autonomy over her obtained ova. In so doing, the ethical principle of autonomy that is enshrined in the Act becomes blurred and diluted.

D. 2: Borderless reproduction: the complexity of international surrogacy

Papers 8 and 9 rest on a legal analysis of law, statute and policy informed by my innovative examination of parental registration information for surrogate births. They reveal the importance of social science information in understanding the extra-territorial reach of the fertility business internationally and the implications of its mobility for Canadian surrogates and domestic assisted reproduction policy and law. This work brings full circle my critical investigation of legislative and regulatory gaps and the inconsistencies that render Canada's reproductive law morally incoherent.

[67] Laurie (n50) at 69.

Canada's AHR Act prohibition on the payment by intended parents of Canadian surrogates has no extra-territorial reach.[68] This aspect, together with access to a publicly funded health care system, right to equal medical treatment regardless of gender or marital status, and physical proximity to the U.S. for treatments banned in Canada (such as sex selection), makes Canada an attractive reproductive destination for non-resident intended parents. Moreover, Canada's pull factor has increased given recent bans imposed by countries such as India, Vietnam and Nepal. Other nations such as the U.K. and some U.S. states impose residency requirements which impede access to domestic surrogacy services. The paper argues that non-Canadian residents should be discouraged, if not banned, from making Canadian-based surrogacy arrangements. Drawing on the work of Wertheimer,[69] the paper contends that non-Canadian resident intended parents have an unfair advantage in that they can pay a surrogate without fear of criminal sanctions. This option is not available to Canadian residents.

The paper exposes once again the morally incoherent nature of Canada's assisted reproduction legislation, a situation made ever more problematic by the proposed 2018/19 regulations on surrogate reimbursement. As noted in the joint submission made in January 2019 to the Health Canada consultation by a group of Canadian lawyers, ethicists and political scientists regarding the proposed draft regulations: "it is currently unclear how the Act and *Reimbursement* regulations will apply to

[68] Claire Fenton-Glynn, Outsourcing ethical dilemmas: Regulating international surrogacy arrangements. (2016) 24(1) *Medical Law Review* 59.
[69] Alan Wertheimer, *Exploitation* (Princeton University Press, 1996) Chapter 4: Surrogacy.

intended parents, surrogates or donors who live outside of Canada. As Pamela White has documented, there are an increasing number of Canadian women who act as surrogates for foreign intended parents. While we are not advocating either for or against extra-territoriality, given the consequences of violating the Act (a large fine or a prison sentence), such clarification is needed."[70]

As Paper 9 reveals, other nations have taken a more legally restricted approach. In the U.K., for example, the Parental Order process permits review of the reasonable expenses provision of the *Surrogacy Arrangements Act* 1985 a process it could be argued exerts a measure of oversight over the monies received by U.K. surrogates to cover their expenses. Canada, by failing to regulate surrogacy expenses, provides no such control mechanism. The uncertainty lived by surrogates regarding expenses forces the activity underground and generates the perfect opportunity misuse. No extra-territorial reach in law and the option of easy access to U.S. fertility services where payment to a Canadian resident surrogate could occur creates loop holes and opportunities for malfeasance. This can occur when the Canadian surrogate travels to the U.S. to receive the IVF treatment. It is relatively easy for Canadian surrogates to cross the border, and many Canadians, not just surrogates, do so to access fertility services.[71]

[70] Vanessa Gruben et al., Submission to Office of Legislative and Regulatory Modernization Policy, Planning and International Affairs Directorate Health Products and Food Branch Health Canada January 10, 2019 1-21 at 16.
[71] Aaron Levine et al., 'Assessing the use of assisted reproductive technology in the United States by non–United States Residents' (2017) 108(5) *Fertility and Sterility* 815.

An important contributor to the growth of international surrogacy in Canada has been the privileging of "altruistic" surrogacy, as it is a criminal offence to pay a surrogate.

The paper, co-authored with Karen Busby, questions the trope that commercialisation is the most exploitative feature of the practice. Given the AHR Act's emphasis on the importance of autonomy and consent, we ask about the ability of surrogates to give informed and voluntary consent and to exercise agency in decision-making about treatment decisions and lifestyle changes requested by intended parents. We question the opportunity of Canadian surrogates to develop ongoing relationships with intended parents. When exploitation is understood in this context, the dichotomy between paid and unpaid surrogacy becomes a false one, especially when it revolves around notions of a 'fair amount' and whether the amount exerts a coercive influence on surrogate participation. We contend that non-payment and reliance on altruistic motivation are also risks, offering an opportunity for exploitation, especially when combined with little regulation. This example yet again underscores the legally incoherent position adopted by the AHR Act.

Paper 9 argues that Canada should actively discourage, if not ban, cross-border surrogacy. Meeting the needs of non-resident intended parents means that childless Canadians are less likely to find a Canadian surrogate. A Canadian residency restriction would promote fairer use of scarce health care resources. Restrictions on non-Canadian resident intended parents would address the unfair advantage that they enjoy if they offer fees payable offshore. Closing Canada to international surrogacy

may prompt other nations to reconsider their own legal and policy stance on surrogacy; they will be less able to depend on Canada as a safety valve.

Concomitant with the advantage accorded to non-Canadian resident intended parents is the disadvantage experienced by Canadian surrogates—the only actors in the process unable to receive financial compensation. We argue that commercial surrogacy would remedy the unfair position of surrogates. This approach could increase the number of women willing to be surrogates and alleviate the current shortage; one that has been exacerbated by international demand.

Like my other work, this paper identifies reproductive harms. It provides a structured argument in defence of decriminalising commercial surrogacy. It highlights what appear to be contradictory ethical stances embedded in the AHR Act. On the one hand, commercialisation is derided for its exploitative potential yet, as this paper shows, altruism leaves Canadian surrogates vulnerable to unfair practices. These unintended consequences of a changing surrogacy and assisted reproduction landscape have implications for lives of surrogates lived in the law and regulation. They also highlight the inadequacies of Canada's AHR Act.

D. 3 Why we don't know what we don't know

Underscoring much of my published work advanced for the PhD by publication has been the questioning of 'why we don't know what we don't know' about assisted reproduction and, in particular, surrogacy. As described in the section on

Methodology above, I have looked at the question from a data production perspective, notably the manner in which assisted reproduction registries and vital statistics registries mask surrogate encounters with fertility medicine and parentage. I have made strong recommendations for research to be conducted in Canada with surrogates. I have advocated the examination of Canada's assisted reproduction registry.[72] I strongly recommend that CARTR Plus be taken over by a public health organisation and that it be made to conform to WHO standards.

The genesis of Canada's lack of knowledge about assisted reproduction practices and outcomes stems from the decision made by the SCC of Canada to strike down ss.16-19 of the AHR Act 2004. I argue that the ethical principle of beneficence cannot be met without there being a registry that is accountable to Canadians, including the children conceived as a result of assisted reproduction techniques. My findings regarding the management of ignorance and its continuation due to a lack of regulation is one of the major strengths and contributions of my published work.

E. CONCLUSION

CANADA'S MISSHAPEN REPRODUCTIVE LAW---MORALLY COHERENT AND EVIDENCE BASED?

My published research examines Canada's reproductive law to reveal a legislative framework that is neither morally coherent nor evidence-based. Empirical and

[72] A major SSHRC grant has been awarded for the qualitative and quantitative research on surrogacy in Canada. I am a co-applicant in this four year grant (2019-2023).

statistical investigations of fertility clinics' compliance with soft regulations established by medical bodies reveal deficiencies that are potentially harmful to surrogate mothers and their offspring and which generate regulatory gaps for those who store eggs and embryos. The recasting of traditional surrogacy when undertaken via IVF as a health evil fails to meet the test set by the SCC in *Ref re AHR*. My findings shed light on the nuanced boundaries of vulnerability experienced by fertility patients and surrogates. These analyses demonstrate the value of investigating by means of empirical and statistical research how lives are shaped by law. These approaches enable a critical examination of liminal regulatory spaces including the analysis of vulnerabilities and gendered harms.

In my work, I ask legal scholars to question how information and knowledge about surrogacy practices and outcomes are obtained, managed and used in law and policy-making. My findings uncover the normative shaping of the concept of 'patient' by embryological science and fertility medicine. I demonstrate how the focus on the embryo and the infertile patient concentrates the scientific and clinical gaze on the intended parents rather than the surrogate who undergoes the pregnancy and delivery on their behalf. I argue for greater attention regarding how scientific knowledge is generated[73] and used in the service of the law. My submitted work reveals that existing information about assisted reproduction is insufficient for law- and policy-making, especially given rapid changes in fertility medicine and the growing demand

[73] See David S. Caudill, Chapter 8 Conclusion: A New Picture of Science in Law' in *Stories about Science in Law: Literary and Historical Images of Acquired Expertise*. (2011) Farnham: Ashgate Publishing 137.

for surrogacy services by those in Canada and abroad. These studies indicate the need for more research on the outcomes of fertility medicine for all patients and give scholarly weight to empirically based explorations of experiences of patients (gamete donors and surrogates).

As for the future of Canada's misguided and morally incoherent AHR Act, the proposed 2018 draft AHR regulations have the potential to exacerbate, rather than to mitigate, this incoherence.[74] The proposed Safety of Sperm and Ova regulations perpetuate the existing gendered harms that the Act produces by blurring the definition of donor.[75] There remains a lack of clarity regarding the ability of the traditional surrogate to exercise control over the use of her 'obtained' ova. The proposed 2018 draft Regulations also fail to address the need for evidence-based decision-making, though it must be admitted that without provincial cooperation on this front there is little the federal government can do to remedy this vexing situation. This is where the crux of the matter lies. Unless the federal government steps forward to initiate a provincial/federal dialogue aimed at seeking cooperation and harmonisation, little can be expected to change.

Canada's AHR Act 2004 (amended 2012) relies on criminal law. Its restricted scope post *Ref re AHR* gives it limited regulatory scope. The Act's approach is punitive and its remit is narrowly focused on a few prohibited activities over which the federal government can exercise criminal code authority, such as commercial gamete

[74] Canada Gazette Part 1 (n3).
[75] Canada Gazette Part 1 (n3). See Paper 2 for a fulsome discussion of this item

donation and surrogacy, and use of unscreened sperm and ova. It lacks legislative ability to adapt to changing social conditions and situations. As a result, the statute as currently drafted cannot address emerging issues such as mitochondrial DNA transfers and genome alteration (CRISPR-CAS9) or the growing demand for preimplantation genetic diagnosis.[76]

It is regrettable that there appears to exist so little opportunity for a revamping of the Act. If this were to occur, my work suggests that a return to consideration of the ethical principles that function as a foundation to the legislation would be a good point of departure. Currently these principles exist merely as an unenforceable statement of good intentions. Canada would have a national donor registry had the SCC established that the beneficence principle had constitutional legislative purchase. As well, data on treatments and outcomes could have been collected in a transparent manner with findings and research analysis being used to develop law and policy. With legislative change, there would be an opportunity to entertain a discussion on federal decriminalisation of commercial surrogacy and gamete donation. I argue that there are ways to compensate surrogates and donors for their services without creating an international market in babies and bodies. These are the challenges facing reproductive law and policy in Canada.

[76] The AHR Act is silent on PGD. No province has regulated it.