An Ethical Analysis and Review of Canada's Policy Proposals for Reimbursing Gamete Donors: A Patient-Centered Care Perspective

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April 2019

A thesis submitted to McGill University in partial fulfillment of the requirements of the degree Master of Science.

Abstract

Eleven years following the Canadian Royal Commission on New Reproductive Technologies, the Assisted Human Reproduction Act received Royal Assent in Canadian Parliament ("Assisted Human Reproduction Act," 2004). Among the controlled activities was the prohibition of purchasing either sperm or oocytes. However, section 12 allows gamete donors to be reimbursed for donation-related expenses in accordance with regulations. Health Canada (HC) announced their intent to develop and enforce these regulations in 2016.

The objective of this thesis was to analyze Health Canada's proposed policy for reimbursing gamete donors using a patient-centered ethical framework. A literature review of the ethics of care and patient-centered care identified principles of patient-centered care to apply to HC's proposed policy. The analysis found that the proposed regulations uphold some ethical obligations of patient-centered care, but the definition of an exclusive list of reasonable expenditures and a delay in the development of these regulations did not fulfill the values of respect for autonomy and care.

A "systematic search and review" method was used to compile and qualitatively analyze available health policy ethical review tools. Of the 13 tools identified, two were employed for the analysis of the proposed section 12 regulations. This ethical review also identified other problems with the proposed policy. In particular, the policy does not sufficiently distinguish between oocyte and sperm donors, which may contribute to continued health inequalities. Additionally, the policy does not allow income loss to be reimbursed to oocyte donors, which undermines access to appropriate medical care and infringes on the patient's ability to lead a healthy life.

This thesis presents a relevant perspective on reproductive health policy in Canada. A patient-centered theoretical framework is valuable for reproductive health policies in order to

appropriately incorporate concerns of intended parents and donors within regulations for reimbursement. Further, these policies govern several patient populations. Thus, it is important that policies regarding patient wellbeing and safety uphold ethical standards of patient-centeredness. Finally, as Canadian policy regarding reproductive health moves forward, it could benefit from continuing the discourse on the moral assumptions made in this field. This thesis may be a useful contribution to the dynamic field of Canadian reproductive health and law.

Résumé

Onze ans après la Commission royale sur les nouvelles techniques de reproduction, la Loi sur La Procréation assistée a reçu la sanction royale par le Parlement ("Loi sur la procréation assistée", 2004). Parmi les activités réglementées, la Loi interdit l'achat d'ovules ou de spermatozoïdes. Toutefois, l'article 12 permet aux receveurs de gamètes de rembourser aux donneurs de gamètes les frais liés au don, conformément à la réglementation. Santé Canada a annoncé son intention d'élaborer et d'appliquer ces règlements en 2016.

L'objectif de cette étude était d'analyser la politique proposée par Santé Canada pour le remboursement des donneurs de gamètes dans une perspective axée sur le patient. Une revue de la littérature de l'éthique des soins et de la théorie des soins axés sur le patient a permis d'identifier les principes des soins axés sur le patient à appliquer à la politique proposée par Santé Canada. L'analyse a révélé que le règlement proposé respecte certaines obligations éthiques des soins axés sur le patient, mais qu'en définissant une liste exclusive de dépenses raisonnables et en retardant l'élaboration de ce règlement, les valeurs de respect de l'autonomie et des soins ne sont pas entièrement respectées.

Une méthode de "recherche et revue systématique" a été utilisée pour compiler et analyser qualitativement les outils d'analyse éthique des politiques de santé disponibles. Sur les 13 outils qui ont résulté de la recherche, deux ont été appliqués à l'article 12 du projet de règlement. Cet examen a permis de cerner d'autres problèmes liés à la politique proposée. En particulier, la politique ne fait pas suffisamment la distinction entre donneuses d'ovocytes et donneurs de spermatozoïdes, maintenant ainsi les inégalités en matière de santé. La politique ne permet pas non plus de rembourser les pertes de revenu aux donneuses d'ovocytes, ce qui compromet l'accès à des soins médicaux appropriés et nuit à leur capacité de mener une vie saine.

Cette thèse présente une perspective pertinente sur la politique de santé génésique au Canada. Un cadre théorique centré sur le patient est important pour les politiques de santé en matière de reproduction afin d'intégrer de manière appropriée les préoccupations des parents et des donneurs visés dans la réglementation relative au remboursement. De plus, ces politiques contrôlent de manière significative de multiples populations de patients et il est important que les politiques concernant le bien-être et la sécurité des patients respectent les normes éthiques de l'approche centrée sur le patient. Cette étude présente une contribution unique dans le domaine dynamique de la santé et droits génésiques au Canada, et permet de maintenir la discussion autour des postulats moraux, à mesure que cette politique canadienne progresse.

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List of Abbreviations

AHR: Assisted Human Reproduction

IP(s): Intended Parent(s)

IVF: In-vitro Fertilization

RCNRT: Royal Commission of New Reproductive Technologies

AHRA: Assisted Human Reproduction Act

HC: Health Canada

EPF: Established Programs Financing

PCC: Patient-centered Care

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Acknowledgements

This thesis was not a sole effort and several people ought to be recognized for their valuable contributions. First, I would like to thank the Canadian Institute of Health Research (CIHR) for awarding me the Canadian Graduate Scholarship and an Institute Community Support Travel Award. I would also like the thank the Department of Family Medicine Graduate Programs at McGill University for awarding me the Graduate Excellence Award for tuition assistance.

I would like to recognize my peers and fellow classmates at the Department of Family Medicine. You have all contributed to my academic and mental wellbeing for the past two years. Thank you for celebrating every victory, for helping me through challenges, and for cheering me on every step of the way. I am extremely lucky to have had this group of people surrounding me with contagious positivity. I am certain that my experience would not have been nearly as enjoyable if you had not been a part of it. For your friendship and support, I am grateful.

I want to recognize my thesis committee members, Professor Bartha Knoppers, Dr. Phyllis Zelkowitz, and Dr. Jennifer Fishman for their expertise and contribution to my thesis. Your feedback and support were invaluable to the final draft of this thesis. I greatly appreciate the time and energy you committed to enhancing my research.

I am extremely grateful for my supervisor, Dr. Carolyn Ells, for the incredible contributions you made to not only this thesis but to my greater success and future. Your dedication to my success was unwavering, providing feedback on countless proposals, protocols, manuscripts, and drafts of this thesis; for providing several letters of recommendation and feedback on my applications for funding. More than that, you supported my overall wellbeing and empowered me as an academic. Thank you for your incredible support, Carolyn.

To my family, I am grateful for your continued support of my goals. Despite 600km between us, I felt capable and empowered because of all of you. I always looked forward to every trip home to visit and to catch up on my progress. I am extremely privileged to have you all as such a strong support system, consistently reassuring me every step of the way. To my grandparents, cousins, aunts and uncles, and especially my brothers, I thank you for your consistent love and encouragement.

Finally, I am greatly indebted to the unparalleled support, love, graciousness, and selflessness of my parents. Their unconditional faith in my abilities and judgement has given me the confidence to pursue all of my goals, large and small. Their commitment to my success will never cease to amaze me, and for that I am forever grateful.

Preface

This thesis was formatted as a manuscript-based thesis. A manuscript-based Master's thesis contains sufficient material for at least one manuscript. This thesis contains the material for two manuscripts, which are in the following chapters: "Chapter 3: Identifying and classifying tools for health policy ethics review: A systematic search and review", and "Chapter 4: Do the Proposed Regulations for Reimbursing Gamete Donors Align with Patient-Centered Care Values? An Ethical Analysis and Review of the Health Canada's Proposed Policy". These chapters are each prefaced individually with their general approach and the contribution of the authors.

Chapter 1: Introduction to the Assisted Human Reproduction Act Within Canadian Health Policy

"When I was born, Patrick Steptoe and Robert Edwards, the two men who came up with the technique, suggested my middle name be Joy. They said my birth would bring joy to so many people.

Forty years, and millions of babies later, many will agree they were right."

- *Louise Brown, The Independent, 2018*

Assisted Reproduction

The use of medical interventions to assist with procreation, known as assisted human reproduction (AHR), has developed at an extraordinary rate for the past 40 years. A 2012 report for Health Canada (HC) suggests that 15% of couples in Canada sought medical attention for help with conception, 19% of these seeking AHR (Bushnik, Cook, Hughes, & Tough, 2012). These numbers can be expected to fluctuate as a result of recent changes to insurance coverage of AHR treatments in certain Canadian provinces (e.g. Ontario, Quebec). The treatments and clinical applications of available AHR procedures are diverse and embrace various patient groups. AHR allows childbearing for those with infertility, a condition with a rate of approximately 16% in Canada (Public Health Agency of Canada, 2013). Using donated embryos and sperm, AHR also helps those who cannot expand their families conventionally, such as single intended parents (IPs) or those who identify as lesbian, gay, bisexual, transgender, and/or two-spirited. IPs with known hereditary diseases may use AHR in an attempt to mitigate the transmission of such conditions. As a result, AHR has served to grow families where this was not previously possible. Due to the expanding applications of AHR, the source of gametes has also

broadened. In-vitro fertilization (IVF) - whereby an egg is fertilized by sperm in-vitro and transferred to a gestational or surrogate mother's uterus, can be performed using either IPs gametes or donor gametes. Evidently, the capabilities of AHR have augmented society in many ways. However, they also introduce new, unprecedented challenges to the realms of science, medicine, law, and policy. Thus, their applications and governance require attentive consideration from scientists and policymakers. In Canada, this attention began in 1989 by the Royal Commission of New Reproductive Technologies.

The Royal Commission on New Reproductive Technologies

Ten years following the first live-birth using in-vitro fertilization, the Canadian government appointed the Royal Commission of New Reproductive Technologies (RCNRT) in 1989. The purpose of the commission was to find evidence that would guide the actions of the government on the matters of assisted procreation. Specifically, "The mandate of the Commission was to conduct a comprehensive study and to report on developments in medical science related to new reproductive technologies, along with their social, ethical, health, research, legal and economic implications" (Norris & Tiedemann, 2015).

The RCNRT aimed to achieve their goal in part by consulting Canadians using telephone surveys, public hearings, and reviewing submitted briefs (Baird, 1996). The Commission also "conducted a research program to examine the issues through projects and analysis in many disciplines, including those of social science, ethics, law, and medicine" (Baird, 1996, p. 26). Through these initiatives, the RCNRT concluded that Canadians greatly valued raising a family and that infertility was not a trivial matter. They also claimed that Canadians were concerned about how new reproductive technologies would be applied in clinical practice and wanted to ensure it would not be misused nor inflict harm (Baird, 1996). However, despite the effort to

consult with Canadians, some claim that their method excluded minority and vulnerable groups at some public hearings (Jones & Salter, 2010). This exclusion may have left out important, under-represented perspectives of those groups from their final report.

The final report released by the RCNRT was named "Proceed with Care". The name reflected their chosen ethical approach. The RCNRT claims to have used the theoretical perspective of ethics of care along with guiding principles to lead their inquiry. They argued that the ethics of care is the most appropriate stance because it is consistency with interdependent relationships that are prevalent in issues surrounding AHR. As such, "[t]he ethic of care means that a large part of ethical deliberation is concerned with how to build relationships and prevent conflict, rather than being concerned only with resolving conflicts that have already occurred" (Baird, Jantzen, McCutcheon, Knoppers, & Scorsone, 1993, p. 50). They also used a set of guiding principles, defined as "… individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability, and balancing of individual and collective interests" (Baird et al., 1993, p. 53). Through the use of guiding principles combined with the ethics of care theory, the RCNRT aimed "…to cast light on issues when conflicts do arise" and to consolidate the underlying similarities of traditional ethical theories (Baird et al., 1993, p. 50). Therefore, their approach consisted of following principles that were situated within a broader ethics of care framework, claiming they were a "concrete expression to the ideal of care" (Baird et al., 1993, p. 52).

In summary, the RCNRT recommended to Parliament the imposition of boundaries on the uses of new reproductive technology and organizing a governing body "for the provision of new reproductive technologies" (Baird, 1996). They suggested that certain reproductive technologies

should be prohibited, including practices that do not align with Canadian values of non-commercialization of reproduction, fair and equitable access, and responsible use of public resources (Baird et al., 1993). They believed that the interests at stake concerning AHR were not limited to individuals but more broadly to Canadian society, requiring a national approach. They also called attention to the inability of private or public organizations to address the moral and scientific concerns surrounding these technologies. The lead on AHR policy, therefore, needed to be taken by an overarching federal structure.

The Assisted Human Reproduction Act

The final report from the RCNRT was consulted to develop the Assisted Human Reproduction Act (AHRA)("Assisted Human Reproduction Act," 2004). In the AHRA, prohibited activities are detailed in sections 5-12. These prohibitions include: using reproductive materials without consent, from minors, or posthumously, creating chimeras, socially motivated sex selection; and purchasing reproductive material. Sections 13-39 of the AHRA describe licencing regulation[1] and sections 40-59 refer to administration and enforcement of the Act.

The Royal Commission recommended that the Canadian government appoint an agency to oversee the implementation of policy and reproductive law (Baird et al., 1993). Accordingly, the AHRA mandated the agency Assisted Human Reproduction Canada was formed to undertake these duties. Specifically, it would be "responsible for a wide range of activities related to AHR, including issuing and reviewing licenses under the AHRA, compliance and enforcement, and collecting, analyzing and managing health reporting information" (*Health Canada, 2017*). It was established in 2006 and the board was assigned in 2007 (Jones & Salter, 2010). However, due to

[1] These sections were repealed in 2012 based on the Supreme Court Ruling that they were *ultra vires* the Federal government.

federal budget cuts, the agency's closure was announced in 2012 (Baylis & Downie, 2013; Cattapan & Cohen, 2013).

The government followed the Commission's footsteps by developing the AHRA using ethical principles rather than a particular ethical theory. The final Act included seven guiding principles (section 2) that were intended to support the provisions of the Act. They are:

a) "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;

b) 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;

c) 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;

d) the principle of free and informed consent must be promoted and applied as a fundamental condition of the use of human reproductive technologies;

e) persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their sexual orientation or marital status;

f) 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

g) human individuality and diversity, and the integrity of the human genome, must be preserved and protected.” ("Assisted Human Reproduction Act," 2004)

These exact principles do not guide the analysis in this thesis, but they are important for understanding how consistent the Act and the proposed regulations are within the existing AHRA framework.

Following the assent of the AHRA in 2004, Quebec swiftly challenged it and claimed certain sections were unconstitutional. The Attorney General of Quebec challenged 32 provisions by submitting an appeal to the Quebec Court of Appeals, questioning whether the AHRA impinged on provincial jurisdiction and was therefore unconstitutional (Norris & Tiedemann, 2015). The Quebec Court of Appeals upheld this challenge and ruled the AHRA unconstitutional in 2008. The Attorney General of Canada appealed this decision. In 2010, the case went to the Supreme Court of Canada, where the original decision was mostly upheld (Cameron & Gruben, 2011; "Reference Re Assisted Human Reproduction Act," 2010). The Act was amended accordingly in 2012, resulting in the repeal of sections 13-43. In light of the AHRA, Québec passed a separate Bill for reproductive technologies in 2004 (Bill-89). This bill was introduced by Quebec Health Minister Phillipe Couillard. It indicates that “[t]he object of this bill is to provide a supervisory framework for clinical and research activities relating to assisted human reproduction in order to ensure high-quality, safe and ethical practices. The bill is also designed to encourage the ongoing improvement of services in this area” (Couillard, 2004, p. 2). Quebec remains the only Canadian province to have provincial legislation governing reproductive technologies.

Recent Proposals for the AHRA Regulatory Framework

Despite the development of reproductive technologies and their clinical applications in Canada, the Act's provisions have remained unchanged since their assent in 2004[2]. In 2016, Health Canada (HC) announced their plans to address key regulatory gaps in the AHRA. They released their first report in July 2017 outlining the information and feedback they received from stakeholders including infertility patients, experts, and physicians (*Health Canada*, 2017). This document presents three regulatory policy proposals: 1. Product Safety[3], 2. Reimbursement, and 3. Administration and Compliance[4]. Following the release of these proposed regulations, HC reached out to relevant stakeholders for feedback. Considering HC's engagement with stakeholders on their proposed policies, this an ideal opportunity to provide HC with the results of a scientific examination of influential reproductive health legislation. This thesis will focus on analyzing the policy proposals specifically made regarding section 12, which addresses reimbursement to gamete donors.

Proposed Regulations Surrounding Gamete Donor Reimbursement

Currently, section 7 of the AHRA prohibits compensation or payment for egg or sperm donations, while section 12 is interpreted to allow eligible expenditures to be reimbursed according to specific regulations. However, these regulations referred to in the Act have not been developed since the assent of the AHRA. HC has proposed a policy to regulate the

[2] The only revisions to the Act since 2004 were the 2012 amendments made in light of the Supreme Court of Canada's ruling on the constitutional validity of certain sections of the Act.
[3] Product safety pertains to section 10 of the AHRA and regulates criteria and requirements for sperm and ovum to be safely imported and used in Canada.
[4] Administration and compliance refer to sections 45-58 of the AHRA. The purpose of these regulations is to "establish a regulatory framework for compliance verification by designated inspectors, as well as and enforcement activities in relation to the Act" (*Towards a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals*, 2017).

reimbursement of gamete donors for their expenses related to the donation process. Once these proposed regulations are enacted, section 12 will be brought into legal force.

Due to the criminal nature of the AHRA, regulations pertaining to the Act must respect the provisions of the Act. As a result, HC cannot implement regulations that would conflict with any legal provision in the Act. To do so, the Act would need to be amended before such regulation could be implemented and enforced. At this time, HC is not revisiting the criminal prohibitions of payment for surrogacy or gamete donation. However, this is a contested area in the Canadian AHR context. Scholars have pointed out that Canada has inadequately enforced this prohibition (Nelson, 2013). Downie and Baylis (2013) claim that several prohibited activities are currently taking place in Canada, such as payment for eggs, payment for services such as surrogacy, and reimbursement to gamete donors for expenses with and without receipts[5]. Outside Canada, compensation for gamete donation has been argued to be ethically justifiable given that monetary gain compensates time and risk and the payment is not for the gametes themselves (Daar et al., 2016). Others claim that countries like the United States have not given the same attention as Canada has regarding concerns of commodifying human tissue or gametes (Ikemoto, 2016). Despite such arguments, HC is taking steps to propose only a regulatory framework for reimbursements and are not considering legalizing payments for gamete donation or surrogacy at this time. As such, this thesis will specifically focus on the ethical implications of the proposed policies for reimbursing gamete donors.

[5] Reimbursement, in the current framework is legally unclear. Since section 12 requires regulations, and these regulations do not exist, Downie and Baylis (2013) argue that any reimbursement is illegal. However, they indicate that others have argued that without regulations, it is legal and there are simply no provision on what is reimbursable.

Canadian Healthcare Policy

Beginning in 1945, the Canadian government began debating a proposal of what eventually became a publicly funded healthcare system across every province and territory, along with laws and policies that govern healthcare administration and services ("Canada's Health Care System," ; Taylor, 2009). These events uprooted healthcare services from the private system into the government system, exposing healthcare to the influences of the shifting power between the federal and provincial governments. As a result, healthcare policy is influenced by several features of Canadian society. It is important to appreciate not only the effects of the economic structure of society but also to recognize the constraints introduced by the political and institutional systems when studying public policies (Atkinson & Chandler, 1983). This is relevant when looking to Canadian healthcare policy, particularly assisted reproduction policy.

Since 1977, the provinces acquired greater responsibility for the administration and financing of their healthcare system due to the Established Programs Financing (EPF) Act. Prior to this, the Medical Care Act (Medicare) required the federal government to pay for 50% of each province's universal, public medical insurance. Under the EPF Act, the Federal government pays the provinces based on national per capita product rather than sharing a percentage of health insurance cost (Madore, 1991). However, as there has historically been tension between federal and provincial power in Canada, and once healthcare became publicly funded by both levels of governments, these tensions were more obvious within healthcare policy (Jones & Salter, 2010). The EPF Act gave the provinces more responsibility for healthcare policies within their jurisdiction, which was more aligned with the constitution, in which it states that healthcare administration falls under the provincial jurisdiction (Canadian Constitution 92(7)).

In 1985, the Canada Health Act was passed, in a continued effort to clarify the provisions of healthcare within Canada. The Canada Health Act defines the purpose of Canadian healthcare policy "…to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers" ("Canada Health Act," 1985). In order for provinces to receive federal funds for healthcare, the provinces insurance plan must meet the criteria of: "(a) public administration; (b) comprehensiveness; (c) universality; (d) portability; and (e) accessibility" ("Canada Health Act," 1985).

As a result of the funding structure of healthcare and constitutional jurisdiction, provinces typically implement their own healthcare policies, including their distribution of funds, delivery of services, and system administration processes ("Canada's Health Care System,"). However, Cameron and Gruben (2011) point out that the separation between provincial and federal governments are often litigated in cases where the Constitution cannot clearly distinguish policy and legal responsibilities. Jurisdiction, between the federal or provincial government, depends on whether the purpose of the law falls within the criminal law power of the federal government or the health services administration jurisdiction of the provincial government (Constitution Act, 1867).

Regarding the AHRA, the Constitutional divide between the federal and provincial government was not easily distinguished and was contentious in the Supreme Court. The ambiguity of healthcare policy regarding the provisions of provinces and Parliament made it difficult to decide who is responsible for implementing and enforcing AHR policy. For the judges in favor of Parliament, their reasoning was that "[t]he dominant purpose and effect of the legislative scheme is to prohibit practices that would undercut moral values, produce public

health evils, and threaten the security of donors, donees, and persons conceived by assisted reproduction" ("Reference Re Assisted Human Reproduction Act," 2010). For judges in favour of Quebec, they reasoned that "the purpose and the effects of the impugned provisions relate to the regulation of a specific type of health services provided in health-care institutions by professionals to individuals who for pathological or physiological reasons need help to reproduce" ("Reference Re Assisted Human Reproduction Act," 2010). In the deciding vote, the judge claimed that some of the challenged provisions were indeed not valid because they regulated medical practice and delivery.[6] However, the judge ruled some of the challenged regulations as constitutionally valid[7] because they were relevant to the criminal sanctions of the AHRA ("Reference Re Assisted Human Reproduction Act," 2010).

The AHRA is unique legislation because it applies federal control within the healthcare system, and in some cases, within the private market. The potential impact that AHR has in medical, moral, and social realms has cemented its position in Canadian health policy and law. AHR receives policy attention due to its perceived impact on public interest, such as the RCNRT suggestion that AHR should be government regulated to ensure it is delivered in accountable ways. This suggestion implies that these technologies have the capacity to be abused by members of society and that this would be detrimental to public safety (Norris & Tiedemann, 2015). It also reflects the movement of "policy that deal[s] with "deep-seated moral codes." (Dave Snow, 2013, p. 171). Regulations that control assisted reproduction, argued by Dave Snow (2013), "constitute legal sanctions of right and wrong that validate a particular set of fundamental values" (p. 172). Thus, AHR policy is not only a regulatory approach but suggests an ideological stance on what constitutes moral versus immoral activity.

[6] Sections 10, 11, 13, 14 to 18, 40(2), (3), (3.1), (4) and (5), and 44(2) and (3).
[7] Sections 8, 9 and 12.

Public Health Ethics

The ethics of public health and health policy is attracting more attention from bioethicists in recent years. Health policy ethics addresses moral issues of practices and policies that focus on broader-level interventions in public and population health (Abbasi, Majdzadeh, Zali, Karimi, & Akrami, 2018). Due to the wide-encompassing scope of public health, the ethical concerns that arise in this field are unique. As a result, the normative practices and standards need to be applicable to the ethical particularities of public health (Baum, Gollust, Goold, & Jacobson, 2007). Dawson (2011) distinguishes between public health and clinical medicine, using the phrase "nature of public health condition" to assert that public health is fundamentally different from clinical medicine (p. 2). Accepting this condition implies that the nature of good within public health endeavours is different from clinical medicine or medical research and that it may be inappropriate to apply the same frameworks and assumptions (Dawson, 2011). To ensure informed ethical scrutiny of health policy issues, one should be cautious to avoid combining the ethics of public health with the clinical ethical norms.

Assisted reproduction is an important public health issue due to the prevalence of infertility and the rise of specialized treatments, which creates a conflict between medical advancement and public safety and health. As with other public health policies, assisted reproduction policy in Canada was focused on "…health as a common good" (Baum et al., 2007, p. 658). The Royal Commission was "Mandated to study and report on the broad 'social, ethical, health, research, legal and economic implications' of reproductive technologies…[and] also included a focus on the protection of women's health" (Campbell, 2002, p. 203). As a result, the AHRA was strongly justified by its goal to protect the health and welfare of those impacted by AHR ("Assisted Human Reproduction Act," 2004). However, Blyth and Farrand (2005) argue that jurisdictions

may introduce assisted reproduction regulation for reasons unrelated to these public health goals, such as religious reasons or the lack of resources. These reasons would need further ethical justification, seeing as they do not clearly uphold the goals of public health. Public health ethics attempts to achieve this, by ensuring that public health goals are ethically justified (Bernheim, Nieburg, & Bonnie, 2007). As Canada introduces new policies for gamete donor reimbursement, it is important to address their ethical permissibility. Thus, public health ethics is relevant for reproductive health policy in order to ensure Canada's policies have appropriate ethical justification.

Ethical analysis of health policy is a key component to achieve effective and good public health (Petrini, 2010). It is becoming more common for ethicists to be involved in policy making and analysis (Giacomini, Kenny, & DeJean, 2009). Further, an inquiry into the application and function of ethics in health policy is growing (Grill & Dawson, 2017). A. Frolic et al. (2012) reviewed the literature on the health policy review processes of health ethics committees and identified five themes: 1) health ethics review had positive outcomes on policy, 2) a lack of transparency of processes, 3) the need for rigorous processes to support ethical analysis of policies, 4) importance of the collaboration in ethics policy work, and 5) the importance of evaluating policies and the review processes. These themes highlight the importance of including health policy ethical analysis in institutional policy review and could have in some higher-level policy.

Given the importance of ethical analysis of health policies, the policy for reimbursing gamete donors may benefit from an ethical review. Applying an ethical review tool for health policy may be a useful, reproducible, and traceable approach to this task. Using a specific tool could help ensure that the analysis 1) is clearly understood by all stakeholders, 2) is based on

theoretically sound approaches, and 3) contributes to the general field of health policy ethics by demonstrating the use of a framework and ethical review tools in a practical setting.

Implications for Primary Care

As the proposed regulations from HC for reimbursing gamete donors are discussed with stakeholders and are implemented, it is important to consider the implications these regulations will have for primary care physicians. The act and the policy that governs its implementation impact how primary care physicians advise their patient regarding AHR treatment options for infertility, as well as how their patients seek and receive AHR. Primary care involves the dimension of continuity and coordination of care (Audet, Davis, & Schoenbaum, 2006; *Patient-Centred Primary Care in Canada: Bring it on Home*, 2009). In order to achieve continuity of care, primary care physicians should be aware of the policies for reimbursing gamete donors in order to provide support for their patients who donate and receive gametes. In addition, patients seeking donor gametes or donating their gametes must navigate the healthcare system to receive this care. Primary care physicians, by virtue of their responsibility to help coordinate care, can assist in the navigation of the system more effectively if they are aware of the regulation of these services. These dimensions of primary care demonstrate that it is valuable for primary care physicians to be knowledgeable in the policies of AHR and clarifies why this research relevant to their work.

Research Question

HC's renewed efforts to develop regulations for reimbursing gamete donors raises questions regarding the ethical implications of these policies. This thesis will attempt to address the question of how well do HC's proposals for Section 12 (which pertains to the reimbursement

of gamete donors) align with the values and principles of patient-centered care (PCC) and what are the ethical implications of these proposals?

The purpose of addressing these questions is to provide valuable normative input to the field of reproductive medicine and policy, as well as to demonstrate that PCC can be applied as a theoretical framework for analyzing healthcare policy. Moreover, this thesis may add to the existing literature on healthcare policy ethics and public health ethics by contributing a literature review on the tools available for healthcare policy ethics review.

Thesis Objectives

The primary objective of this research is to use a PCC theoretical framework to analyze HC's proposed regulatory framework for reimbursing gamete donors and to assess its ethical implications. In doing so, these regulations will be assessed using an ethical framework that prioritizes patients and illuminates patient concerns within reproductive health policy and services.

The secondary objective of this thesis is to determine what tools are available to undertake an ethical review of healthcare policy. The overarching aims of this thesis were to understand the current scholarship on health policy ethics, to ethically analyze the Canadian regulatory policy proposals that will impact gamete donors and IPs, and to critically assess some of the regulatory landscape of assisted reproduction in Canada.

Thesis Outline

In the chapters that follow, the thesis objectives are addressed over several steps. The first step involves defending the application of PCC as a theoretical stance for the analysis. Chapter two is an introductory literature review that summarizes the major scholarship on the ethics of care and PCC theory. The structure of the literature review is as follows: first, the major

contributors to ethics of care and their contributions are examined. Then, PCC literature is summarized, revealing the overarching principles and values of PCC. Parallels between ethics of care and PCC are drawn and the applicability of PCC to address ethical dilemmas of reproductive medicine and policy is demonstrated.

Chapter three follows a systematic search and review method to search and analyze healthcare policy ethical review tools. The tools are analyzed using qualitative content analysis, a method that assigns text data to qualitative categories. The tools are coded for their ethical priorities/values, the ethical theory that is prevalent or influencing, and their scope of applicability (e.g. institution or government). The structure of each tool is qualitatively described. The tools are organized along with their qualitative categorization by ethical priorities or values, prevalent or influencing ethical theory, and their scope of applicability.

Chapter four elaborates on the current knowledge in the field of reimbursing and commercial gamete donation. This summary is followed by an ethical analysis of HC's proposed policies. Then, two review tools that were identified in Chapter three are used to review HC's proposed policy for reimbursing gamete donors. The analysis was conducted as follows: The current state of regulation regarding reimbursing gamete donors and the proposed policy changes to reimbursing gamete donors are outlined. Then, the changes are assessed to determine if they align with the ethical values of PCC and the two ethics review tools are used to analyze the policy proposals. The final chapter presents and discusses the overall findings, including the potential implications of the findings on the future of reproductive policy in Canada and health policy ethics in Canada.

Chapter 2 Literature Review: Patient-Centered Care as a Theoretical Framework for Ethically Analyzing Assisted Reproduction Policies in Canada

Introduction

Patient-centered care (PCC) is primarily regarded as a specific approach to medical practice (J. H. Robinson, Callister, Berry, & Dearing, 2008). Yet the moral motivations, intentions, and goals of PCC suggest that it is also a theory of ethical practice (Epstein & Street, 2011; Mead & Bower, 2000). Its underlying assumptions about the various obligations of healthcare providers to their patients distinguish it from other methods of practice as a moral approach to care (Entwistle & Watt, 2013). Similarly, the ethics of care is a moral philosophy that is grounded in the importance of relationships and the deconstruction of marginalizing social norms (Held, 2005). The theoretical claims of ethics of care help clarify the ethical justifications of PCC. This makes PCC a more practical, relationship-based ethical lens for analyzing healthcare and patient-centered issues, such as assisted reproductive medicine.

The purpose of this chapter is to explore the moral features of PCC and to justify it as a theoretical framework to analyze policies governing assisted reproduction, specifically gamete donor reimbursement, in Canada. The questions that this chapter aims to answer are: How does the ethics of care help us navigate the philosophical assumptions of PCC, and what makes PCC an appropriate framework for addressing the policies surrounding reimbursement of gamete donation? These questions will be answered by reviewing and summarizing the literature on the theory of ethics of care and PCC. The objectives here are 1) to explore the broader philosophical parallels that PCC has with the ethics of care and 2) to justify the use of PCC as a theoretical framework in the analysis of gamete donor policies. This review will extract important values and principles from prominent literature in the field of PCC. Following the literature review, it

will be justified why PCC is an appropriate framework to approach ethical issues of reproductive health and assisted reproduction policy.

This chapter sets the philosophical groundwork for the analysis of health policy ethics review tools and the analysis of Canadian policy proposals for reimbursing gamete donors in the following work. In chapter three, a systematic review of health policy ethics review tools is presented. The values that are identified from the literature on PCC in the current chapter are used to direct the qualitative coding of the policy ethics review tools of chapter 3. In addition, these values guide the critical ethical analysis of the proposed policies by assessing the alignment of these proposals with the PCC values in chapter four. Thus, the research in this chapter is needed to establish an ethical and conceptual framework to approach the primary objective of this research, which is to ethically analyze HC's proposed policy framework for reimbursing gamete donors.

Methods

Two introductory literature reviews were conducted in order "…to identify the prominent concepts and important findings that have shaped the topic" (McDougall, 2015, p. 524). The literature review here will outline the existing theory and knowledge of ethics of care, or care ethics (synonymous) and PCC in order to answer the research questions. The primary database used for these searches was PubMed, in order to capture the most prominent scholars in both of these fields, which are predominately biomedical. The key words for the review of ethics of care were "ethic of care", "ethics of care", "feminist ethics of care", "theory/theoretical", "philosophy/philosophies", and "care ethics". The key words for PCC search were "patient-centered care", "patient-centered care theory", "person-centered care". All key words and

databases were chosen by the student with the assistance of a subject area librarian. Patient-centered literature was identified with the help of the student's supervisor (C.E.).

The Ethics of Care

Table 1: Summary of major contributors to the development of ethics of care.

Author	Year	Major Work Contributed
Carol Gilligan	1982	In a Different Voice
Sara Ruddick	1980	Maternal thinking (Article)
	1989	Maternal Thinking: Toward a Politics of Peace (Book)
Nel Noddings	1984	Caring: A relational approach to ethics and moral education
	2002	Starting at Home
Tove Pettersen	2008	Comprehending Care: problems and possibilities of ethics of care
Joan Tronto	1993	Moral Boundaries: A political argument for an ethic of care
	2013	Caring Democracy: markets, equality, and justice
Virginia Held	2005	Ethic of Care: Personal, political, and global
Eva Kittay	1999	Love's Labor

Ethics of care stems from feminist philosophy and ethics, which challenge dominant ethical theories and traditional schools of thought (S. Sherwin, 1992). However, it should be noted that ethics of care is distinct from feminist philosophy and ethics and constitutes its own ethical approach. Carol Gilligan is recognized as a leader in the ethics of care. According to Susan Sherwin (1989), Gilligan "recognize[s] that mainstream ethics has carried on in a voice that is overwhelmingly masculine – the voices of women have been largely excluded or ignored" (p. 58). In her book *In a Different Voice,* Gilligan investigates how disciplines such as psychology, sociology, and philosophy, are formed on the basis of male norms and projected as "sexually neutral" (C. Gilligan, 1982). Her observations in this field informed her proposition that this male bias has delegitimized the female experience of morality and ethical agency, and that features of care such as empathy, dependence, and relationship are equally important ethical principles or virtues.

Virginia Held also contributes substantially to the field of ethics of care, describing three distinguishing features of the theory. First, ethics of care recognizes the moral importance of

relationships, and the relevance of these dependent relationships in ethical decision making. Second, it accepts emotions as legitimate and even encourages the use and recognition of emotions for approaching moral decisions. Third, it denies the validity of using arbitrariness as the standard for ethical reasoning. Instead it suggests that ethical decisions are rightly influenced by responsibilities of care and the contextual factors that contribute to situations (Held, 2005).

Other leading scholars in the ethics of care include Sara Ruddick, Nel Noddings and Joan Tronto. These experts have most fundamentally distinguished ethics of care from traditional ethical theories at the level of personhood, humanity and role of care in moral life. Carse (1998) argues that a prevailing feature of classic ethical theories is "… a commitment to impartiality as a mark of the moral point of view". One of those theories is utilitarianism, which is characterized by the principle of impartiality as a way to maximize the net utility. While this perspective does not overly value the individual, is still does not accommodate actions based on special obligations insinuated by particular relationships (Mill, 1863, p. 10). An opposing, but similarly limited theory is deontology, which is based on an assumption that moral actions must adhere abstract rules (categorical imperatives) that apply equally in all circumstances (Kant & Abbott, 1873). Deontology also does not adequately consider distinct moral obligations based on relationships as ethically valid. Since emotions can be considered subjective, these theories have not considered them appropriate guides to morality. Broadly speaking, these theories tend to use a top-down approach to morality, by theorizing rules and subsequently applying them to moral agents. In contrast to these rule-based approaches, the ethics of care recognizes the social, relational, and emotional contexts that define humanity at its core. The "relational ontology" (Pettersen, 2011) of the ethics of care may allow moral reasoning to begin with the moral agent, followed the development of moral obligations in a bottom-up fashion. It is not "…characterized

by a conscientious adherence to principle…"; rather "[m]oral judgement… can be generated by direct response to another, without any guidance or mediation of categorical considerations" (Carse, 1998). Tove Pettersen (2011) points out how within the ethics of care, the "…relational model allows also for a wider understanding of who the moral agents are" (p. 53). The idea of who the moral agent is in ethics of care is a fundamental difference between this theory and more conventional moral theories (Pettersen, 2011).

"Care" itself may be viewed as a value similar to justice or autonomy, or as a virtue aligned with Aristotle's view of morality. For Held, "actual practices of care… need care as a value to pick out the appropriate cluster of moral considerations" (Held, 2005). Care must hold normative value if people see caring as morally admirable. Pettersen (2011) describes the normative meaning of care as manifestations of non-maleficence and beneficence in two ways. First, it involves broadening the concept of non-maleficence from simply avoiding the infliction of harm to the avoidance and prevention of harm. Second, it involves a restriction of beneficence from doing good to no defined extent, in order to promote good without sacrificing other's or one's own interests. Given that promoting good and preventing harm are values that are ultimately concerned with upholding the interests of the self and others, care implies possessing and acting on the concern for one's self and others welfare while appreciating their interdependence.

The ethics of care also challenges some of the liberalist and neoliberalist ideas that have heavily influenced Western society's definitions of autonomy and individual freedom (Held, 2005). The normative sociological and philosophical shift in human interactions towards liberal values originates from the increased emphasis on individual liberty: the ability to live as a free individual agent without interference by the state or others (Meskill, 2013). Liberal perspectives

tend to harshly critique actions that impede such independent, free will. These perspectives have drawn insights from the philosophies of Immanuel Kant and John Stewart Mill, who generally theorized that sentient humans are rational agents who are able to act autonomously in their moral lives and can make moral decisions based on rationality and universality. The ethics of care, among other feminist and disability perspectives, have recognized the damage that "valuing independence has on women and disabled persons", since "Dependence on others is often humiliating in a society which prizes independence" (Verkerk, 2001, p. 291). Further, Verkerk (2001) claims that care ethics does not abandon the idea of autonomy but promotes autonomy unopposed to relational connections. The ethics of care is distinguished by recognizing the moral agent as legitimate needs of interdependence, as oppose to striving for complete independence. It encourages society to embrace dependence on others and to recognize the moral value of caring for others.

Considering the ethics of care philosophers have focused on how care has been gendered and devalued, the theory has serious implications for societal power, dominance, politics, and justice. The labour of caring in the public domain has often been dismissed because traditionally, women have had to bear caring duties in the private domain. As a result, Tronto (2013) points out that the private sphere has been feminized and the public has been masculinized. The gendering of care has allowed men to "opt out" or not take caring responsibilities as seriously as those whom they are assigned to (Tronto, 2013). Robinson (2011) also explores how women have come to unequally bear the responsibilities of care and the responsibilities of financial security for her family. Since women of colour and lower economic status are disproportionately tasked with care labour, the "politics of caring reveals power inequalities related not only to gender but also to race and locational politics" (F. Robinson, 2011, p. 70). Ruddick (1980)

further outlines the power hierarchies in which care has had a place in, specifically in her seminal article “Maternal thinking”. She explores the benefits of bringing maternal thinking and mothering into the public society. Her essay explains that caring and maternal actions have been subordinated and devalued by dominant pressures and society, rather than being upheld as valid social and moral practices. She also proposes that women inadvertently react to “a social reality essentially characterized by the domination and subordination of persons” in response to “maternal powerlessness” (p. 354). Ethics of care aims to recognize the intrinsic morality of care; to accomplish this, the societal structures of inequality responsible for devaluing care must be acknowledged and challenged.

In summary, the ethics of care is a theory that recognizes care as a vital part of moral life, a necessary practice, and a value of ethical significance. It does not limit care to the traditional space within private life, but claims it has valuable moral consideration and status within philosophy and pragmatic circumstances. It is moves away from normative theories that have dominated philosophical discussions and have typically contributed to the subordination of women’s moral interests. The ethics of care focuses on the caring relationships that are meaningful in people’s moral lives. Ethics of care has its roots in feminist theory, a theory that addresses power imbalances, domination, and oppression that have been perpetuated throughout history. The following sections will use this brief outline of the ethics of care to situate the theoretical underpinnings of PCC and assess how PCC applies to the primary care setting, specifically for the policies governing reimbursement of gamete donors.

Patient-Centered Care (PCC)

PCC is described in the literature as a medical practice that “does not focus solely on the disease or condition, but rather, on the patient and the patient’s psychological, spiritual and

emotional needs" (Reynolds, 2009, p. 133). It also describes it as "health care that is closely congruent with and responsive to patients' wants, needs, and preferences" (Laine, 1996, p. 152). PCC is recognized as an orientation to medical practice that opposes the conventional paternalistic practices of medicine (similar to how ethics of care opposes ethical theories that have subordinated minorities) and embraces the efforts towards autonomous patient decision-making. Patient-centeredness has become a central model in current Western medical practice, and a "core value in family medicine" (Hudon, Fortin, Haggerty, Lambert, & Poitras, 2011, p. 155). The model has been adopted by numerous health advocacy groups and government agencies (J. H. Robinson et al., 2008). A majority of stakeholders in healthcare have recognized the importance of a medical model that focuses on shared decision making and appreciating the whole patient experience.

Other accounts of PCC include McCormack et al. (2011), who describe PCC as "care [that] should be responsive to patient preferences, needs, and perspectives and ensure that patient values guide clinical practices" (p. 1085). Mead and Bower (2000) suggest five dimensions of patient-physician relationship that differentiate the PCC framework from the biomedical approach: the biopsychosocial model, the patient as a person, sharing power and responsibility, therapeutic alliance, and the doctor as a person. Krupat et al. (2001) identify a key element of PCC is "includ[ing] patient-participation and the sharing of power and information between patient and physician" (p. 1057). Overall, the literature on the PCC model endorses valuing patient preferences and their unique perspectives, appreciating the patient's experience of illness, and involving patients as a meaningful stakeholder regarding their care.

PCC is not only a form of practice, or guideline to clinical encounters, but includes obligations, philosophical implications, and suggests truths about right and wrong actions in

medicine. Duggan et al. (2006) argue that "Patient-centeredness is not merely a descriptive account of patient–physician encounters as they actually occur; it is also prescriptive or normative" (p. 272). Epstein and Street (2011) similarly state that "patient-centered care is an approach to care and perceived as the right thing to do" (p. 101). Epstein et al. (2005) differentiates between patient-centeredness as being a moral philosophy, and PCC as "actions in service of patient-centeredness". Further, healthcare professionals must refocus their perspective of PCC as "an ethical encounter with the patient as a person" (Lévesque, Hovey, & Bedos, 2013, p. 36). While it is a pragmatic approach to healthcare and less philosophically encompassing than more normative theories, the PCC framework provides guidance on how one ought to act in particular circumstances and suggests what values should guide one's actions. Values such as trust, patient autonomy, and importantly, care, all lead to a common understanding that PCC is not only a practical medical approach, but that it is a "good" approach.

The literature highlights several values that PCC embodies. A literature review by Hudon et al. (2011) on the dimensions of PCC in primary care, specifically in the context of chronic illness, found six themes: comprehensive understanding of patient experiences, legitimizing illness experience, acknowledging patient expertise, developing partnership, offering realistic hope, and advocacy for the patient. Further, Epstein and Street (2011) refer to PCC values as knowing

> "… persons in context of their own social worlds, listened to, informed, respected, and involved in their care—and their wishes are honored (but not mindlessly enacted) during their health care journey" (p. 100).

While there are several conceptualizations of what PCC entails, there are some common values that emerge from the literature. The next section will identify these values and provide supporting literature for these values.

PCC Values and Principles

To apply the PCC framework to the ethical analysis in this thesis, the values and principles of the approach need to be identified. The brief overview of ethics of care philosophy provided the foundation for delineating, understanding, and justifying values within the framework of PCC. The goal of this section was to identify the values that are of importance to PCC. Four overarching values emerged from the critical review of PCC literature: communication, respect for autonomy and persons, care, and respect for dignity. Assessing the importance of these values for PCC will allow it to be applied in this thesis and in the future as a theoretical framework for health research.

Table 2: Values that are prevalent in the literature of PCC

Value	Supporting Authors	Key message that supports value
Communication	Mead and Bower (2000) Krupat et al. (2001) Epstein et al. (2005) Zandbelt, Smets, Oort, Godfried, and de Haes (2007) J. H. Robinson et al. (2008) Reynolds (2009) Farrell, Kuruvilla, Eskra, Christopher, and Brienza (2009) McCormack et al. (2011) Clayton, Latimer, Dunn, and Haas (2011) de Boer, Delnoij, and Rademakers (2013) BC Ministry of Health (2015) Santana et al. (2018) Constand, MacDermid, Bello-Haas, and Law (2014)	• The "Therapeutic alliance" • Sharing information • Research on Patient-centered communication • Participation influenced by physician communication • Tools are developed to quantify communication
Patient Autonomy	Mead and Bower (2000) Krupat et al. (2001) Davis et al. (2005) Hanson (2008)	• Sharing power • Value of treating "people as persons" • Inform and engage patient in their care

	Epstein, Fiscella, Lesser, and Stange (2010) C. Ells, Hunt, and Chambers-Evans (2011) Hudon et al. (2011) Barry and Edgman-Levitan (2012) Entwistle and Watt (2013) Hammell (2013) Montori, Brito, and Murad (2013) BC Ministry of Health (2015)	• Respect patient autonomy and personal interests • Patient as leader of their care • Shared decision making • Valuing patient preferences • Patient's values guide clinical decisions
Upholding and Promoting Dignity	Hammell (2013) Epstein et al. (2010) BC Ministry of Health (2015) Epstein and Street (2011) World Health Organization (2007) Levinson, Gorawara-Bhat, and Lambs (2000)	• Respect for clients • Respecting patients' needs, values, and personal circumstances • Respect and dignity as a core value • Respect for patients as "unique living beings" • "Patient-centered model of care that demonstrates respect and care for patients"
Care	Ogden et al. (2002) Audet et al. (2006) Beach, Easter, Good, and Pigeron (2005) Stewart (2001) Constand et al. (2014) World Health Organization (2007) Levinson et al. (2000)	• Attention to emotions • Emotional support • Responding to patient fears/emotions • Understanding of patient emotions • "Compassionate care provisions" • Promotion of a "culture of care" helps promote positive outcomes • "Patient-centered model of care that demonstrates respect and care for patients"

Communication

The majority of research on PCC has identified communication as an important and core principle within PCC. Communication fosters essential elements of PCC, including physician-patient relationship, trust, and partnership between the patient and the physician. Effective communication is not only a key component of medical practice, but "[f]or trust to continue and increase, care must be an interactive process between physician and patient" (Reynolds, 2009). Lusk and Fater (2013) stress that "Foundational behaviors of [patient-centered care] include communicating and listening…" (p. 96). Further, Santana et al. (2018) identify communication as a key component in their patient-centered process domains. They claim that, "With effective

communication comes the provision of respectful and compassionate care" (p. 434). Therefore, communication is a vital element to the ethical principle of respect, specifically between the physician and patient.

Empirical studies have suggested that among others, communication is a valuable component of PCC. A review of the literature by Robinson et al. (2008) identified communication as one of the key values of PCC for patient's. Further, De Boer et al. (2013) demonstrated that when PCC was defined by features of communication (i.e. Being listened to, able to ask questions, given appropriate information), it had above-average importance to patients . Zandbelt et al. (2007) found that physician facilitation was important for patient's expression of concerns in a clinical interaction. These examples demonstrate that communication is a core value in PCC.

Communication is viewed here as a practical application of the value of relationships that the ethics of care positions as vital to morality (Held, 2005; Verkerk, 2001). The act of communication is necessarily a relational value, one which ideally strengthens the patient-physician relationship (Mead & Bower, 2000; Reynolds, 2009). Therefore, communication in PCC is an expression of the moral value of relationships that is foundational to the ethics of care.

Respect for patient autonomy and relational autonomy

As PCC views the patient as a whole person, treating them as such demands respecting and understanding patient autonomy. Hammell (2013) addresses how autonomy may seem inconsistent with the ideals of PCC, and that autonomy has been:

> "…construed to be a specifically middle-class, Western assumption that privileges and promotes egocentric notions of individualism and independence

while failing to recognize that all people are interdependent, social beings" (p. 144).

Hammell clarifies autonomy as an important part of PCC by recognizing autonomy is the ability to "manage one's own life" (p. 144). Solely patient-directed care and treatment is not necessary and is not encouraged by the PCC framework. Rather, Epstein et al. (2010) assert that "…patient-centered care fulfills health care professionals' obligation to place the interests of the patient above all else and to respect patients' personal autonomy" (p. 1491).

Entwistle and Watt (2013) further support patient autonomy as important to PCC. They highlight that within PCC patients should be treated as whole persons. This concept has implications for respecting both the dignity and autonomy of patients, since treating people as persons assumes that people are intrinsically important individuals with valuable individual goals. Respect for the autonomy of patients recognizes the value of their goals for their care and their intrinsic importance as human beings. Further, the PCC literature highlights relational autonomy as key to the intrinsic value, rather than individualistic autonomy, since "when preferences are not well informed, stable, strong, or good, or do not relate to issues of importance" (Entwistle and Watt, 2013, p. 31).

Other advocates of including relational autonomy as a core principle in PCC are C. Ells et al. (2011). They find an alignment between the PCC philosophy to treat patients as whole persons within their lived context and relational autonomy's "commitment to the whole person as situated in a complex social context" (p. 89). Further, they highlight that since shared decision making is a core part of PCC, it can achieve the goal of patient-physician collaboration by valuing relational autonomy as the primary model of autonomy. A common theme throughout the literature is the commitment to respecting patient autonomy as a relational concept by

understanding patient's unique context, treating patients as persons, and sharing decision making power.

Respect and upholding dignity

Another prevalent value throughout the PCC literature is respect and respect for dignity. Hammell (2013) describes respect for the patient as having several aspects, such as their preferences, their life experiences, their values, and considering them as inherently worthy of such respect. The expectation to respect patients is an expression of upholding dignity. By understanding that people are worthy of respect and that they are moral beings with moral claims, this sets a precedent for the way that health care providers treat patients from the outset of an interaction. Respecting dignity also introduces the assumption that patients are more than their diseases. Each patient has individual lives with unique circumstances and complex lives, which are not defined by their medical illness. The multifaceted nature of the lived human experience can impact the experience of illness in a myriad of ways, and legitimate attention to this narrative is a part of what distinguishes PCC from the biomedical model (Hovey & Apelian, 2007). The biomedical model has been criticized in the literature for reducing people to diseases that need interventions performed on them and ignoring the intricate context and lives that people come from (Barry et al., 2012; Entwistle and Watt, 2013). In contrast, PCC aims to preserve dignity by recognizing that patients are ultimately humans, who have worth that is not reducible to medical conditions.

The British Columbia Ministry of Health released a report on a Patient-Centered Care Framework (2015) that explicitly identifies dignity and respect as some of the core values in their PCC framework. Their report states "[t]his principle speaks to the need for active listening…and honouring their [patients' and families'] choices and decisions" (2015). Further,

the World Health Organization recognizes dignity as a "universally held value" that person-centered care is rooted in. Upholding and respecting patient dignity is a core value of PCC because it requires physicians to treat their patients as whole people and to avoid reducing them to their disease, which is a defining feature of PCC. Therefore, upholding dignity and respecting people is a value of PCC.

Care as a value and practice

For PCC to be effective and recognized as a uniquely moral approach, the literature suggests that attention should be paid to emotions, and that subsequently these emotions should be addressed in the context of medicine. Audet et al. (2006) report that the Picker Institute include emotional support to alleviate anxiety and fears as an integral part of embodying PCC. Further, Ogden et al. (2002) claims that a defining feature of PCC is "an attention to the affective content of the consultation in terms of the emotions of both the patient and the doctor" (p. 223). Stewart (2001), an important scholar in PCC, identifies caring and attention to emotions as a part of the global definition of PCC. Therefore, attention to and caring for emotions is an important value in the PCC model.

The importance of caring for patients is evident in patient-centered literature, especially since physicians often interact with their patients in times of uncertainty and illness. In a study of fear involving cancer patients, for instance, Beach et al. (2005) observed that for physicians to fully appreciate the biopsychosocial impact of illness on their patients, they needed to approach patients in a caring, attentive way. Further, Mead and Bower (2000) indicate that the "patient-centredness literature focuses mainly on the doctor's role, particularly the skills required in order to achieve and develop the desired emotional `context' in consultations" (p. 1090). The focus on

a biopsychosocial model of health is a priority for PCC and if care is important to this model, then it is also a value of PCC.

The Link between PCC in Ethic of Care

The literature on the theoretical and philosophical basis of PCC has been sparse and inconsistent (Clarke; Lusk & Fater, 2013). The position here is that PCC is consistent with an ethic of care theory. Using ethics of care to understand how the values of PCC are ethically acceptable can facilitate the task of upholding the moral responsibilities of patient-centeredness. The inherent relational nature of PCC makes is consistent with the reasoning of ethics of care. PCC requires communication, bonding, respecting, and understanding between the physician and the patient (Stewart, 2001). The ethic of care also recognizes these values and principles as important and necessary to morality, to the concept of care, and to defining ethical truths. PCC assumes that physicians care about the patient, their experiences, their reality, and their treatment. Philosophically, these facets of PCC are best supported by the ethics of care. That is, the ethics of care is the moral theory that most strongly supports this treatment of patients as ethical obligations.

Further, achieving the goals of PCC relies on the caring aspect of the patient-physician relationship. Reynolds (2009) identifies favorable impacts of PCC, such as adherence to treatment and better health outcomes. When people believe that their health is prioritized and that their input and involvement is valuable, they tend to care for themselves as well. For example, according to Gallagher and Levinson (2004),

"The interaction and communication during the visit shape outcomes, including the post

visit level of trust, the likelihood that the patient will follow treatment recommendations, patient satisfaction, actual biologic outcomes, the potential for malpractice litigation in case of a bad medical outcome, and physician satisfaction".

Sara Ruddick (1998) also theorizes the ways that care is a component of relationships, stating that "As much as care is labor, it is also relationship … caring labor is intrinsically relational." The patient-physician relationship that is foundational to the theory of PCC depends on care and the value of care. Without the value of care, the relationship that is the foundation of PCC would be diminished. Thus, PCC is significantly theoretically justified by the ethic of care.

Using PCC as a Framework for Reproductive Health Policy and Assisted Reproduction

Assisted reproduction policy in Canada should aim to support the PCC values because assisted reproduction, and reproductive health more broadly, is inherently an endeavor that embodies caring relationships and cannot be isolated from such relationships. Addressing reproductive health and AHR policy using PCC values provides a perspective that prioritizes relationships. AHR and reproductive health are fields that directly engage with various relationships and complex emotions. The unique context of reproductive medicine highlights the shortcomings of traditional moral theories in addressing the dilemmas that arise in this field. The position here is that the inability for these theories to take individualized context, emotions, unique relational hierarchies, and the legitimate moral value of care into serious consideration make them less capable of addressing the moral issues within the field. As a result, theories or approaches that envision the human condition as rightfully dependent and emotional, such as PCC, are better suited for application to practices and policies surrounding assisted reproduction.

Sara Ruddick's (1980) work is particularly revealing of the importance of a PCC and the ethics of care framework for assisted reproduction policy. Her thesis is based on how the values

embedded in maternal relationships can substantially contribute to robust ethical thinking in public society. Her thesis stresses how maternal caring responsibilities can be applied to broader social situations by juxtaposing public society to the caring responsibilities and moral reasoning that have been marginalized to the private life of mothers and their families. Reproductive health policy is a prime example of this juxtaposition, since it concerns familial relationships in the clinical and the public sphere. Therefore, when considering the ethics of care from theorists like Ruddick and PCC to be theoretically consistent with ethics of care, there is a logical and beneficial application of the PCC to assisted reproduction.

Assisted reproduction is directly influenced by the "patriarchal practice of medicine" (S. Sherwin, 1989). Medically assisted reproduction can foster oppressive conditions for women based on the physical, social, and political inequalities of reproduction. Further, the historical and present systematic control of women's reproduction should be acknowledged when implementing policies that surround AHR. PCC is a practice that aims to recognize power dynamics and to dismantle their impact on the patient-provider relationship. Thus, the application of its ethical considerations is especially appropriate in reproductive medicine and policy, where power dynamics are especially prevalent.

Care, as perceived by care ethicists and in the PCC literature, is supported as a normative consideration for policies in assisted reproduction. Reproduction is inseparable from relational aspects, such as bearing children and using donated gametes or donating gametes to others. Further, reproductive medicine represents a unique space of public (medical system) and private (family) life, so reproductive medicine is a field that demonstrates the opportunity to bring care, a traditionally private value, into public society. Reproductive medicine requires a sincere trust in a medical practitioner, as patients begin a process that is often full of disappointments and

challenges. Care as an ethical value highlights the ethical importance of the relationship between patients and physicians by instilling a responsibility of care to the physician in order to adequately provide for their patients in these circumstances. It is therefore important to view policies of reproductive medicine through a normative understanding of care.

Communication and upholding dignity are values of PCC that are relevant considerations for reproductive medicine policies. As previously mentioned, reproductive medicine calls for a trusting relationship between the patients and their caregiver. Undergoing assisted reproduction or donating reproductive materials is an emotional experience and there are often underlying circumstances involved, such as infertility or inheritable diseases. This vulnerability implies a moral responsibility on part of the physicians, and the policies that govern them, to uphold and promote patient dignity and ensure their emotional well-being. Further, patients may find it difficult to understand the risks, benefits, and processes of their treatments. It is important to ensure that communication is done in a responsible and effective manner.

More broadly, reproductive health and policy has more direct implications for women than for men; yet institutional power has been historically monopolized by white, middle class men, which has oppressed the ability for women to maintain autonomy in their reproductive health (Held, 2005; S. Sherwin, 1992; Tronto, 1993). Therefore, as S. Sherwin (1989) focuses on, "powerful men in all nations use their institutional authority in the church, the courts, medical societies, and legislatures to set the rules that limit the control women can have over their own reproduction." Care ethics highlights the moral questions that have been traditionally ignored by mainstream society, perpetuating inequality and subordination of women and their agency. PCC is a framework that values understanding patients in individualized contexts, including societal

structures and power hierarchies. Therefore, in a health policy sphere that overwhelmingly impacts women, the use of the PCC framework is fitting.

The value of respect for relational autonomy within the PCC framework is applicable to reproductive policy, since it values the dependent relationships between members of society while recognizing the importance of personal liberties. Public health is traditionally founded on values of utility and the "common good": "From an ethical standpoint, public health activities are generally understood to be teleological (end-oriented) and consequentialist" (Childress et al., 2002, p. 171). However, more recent work in public health has recognized the importance of developing policies that do not unduly interfere on people's lives. For instance, Childress and Bernheim (2015) frame public health ethics as having "…a tentative (but nonabsolute) priority for interventions that do not violate liberty and related norms unless necessary and unless other conditions are met" (p. 7). Others reconcile these concepts by arguing that public health actions should empower the population to live healthy, autonomous lives (Filiatrault, and Désy, 2017). Therefore, respecting relational autonomy within reproductive policy encourages policymakers to consider their policies in the context of both the population and the unique individuals that will be impacted by the policy. This layered ethical approach may allow for policies to be accommodating to unique circumstances without sacrificing the goal of promoting public health and wellbeing.

The benefit of PCC rather than directly applying ethics of care is its applicability and pragmatic approach to applying ethical values in healthcare and healthcare policy. While ethics of care has been referred to in some health care settings, specifically in the Royal Commission for New Reproductive Technologies, these references have been criticized as labelling simple bioethical principles with "ethics of care" with no theoretical substance (Ariss, 1996). Yet this

conflation is not problematic to those who argue that ethics of care is not a distinct theory from the Principle Approach in certain contexts (Edwards, 2011). Still theoretically abstract, the ethics of care may be challenging to apply in the context of reproductive health policy. Despite this, feminist ontology is necessary for ethical reproductive health policy (S. Sherwin, 2002). PCC has the potential to bridge the gap between the abstract, feminist insights of ethics of care and readily applied values within a practice framework.

PCC has garnered international support as the healthcare model and framework to aspire to (WHO, 2007). Specifically, Canada has advocated for the PCC framework for medical care, decision making, and policy. For instance, several provinces have adopted PCC practices (BC Ministry of Health, 2015; Rosser, Colwill, Kasperski, & Wilson, 2011; World Health Organization, 2007). Further, the Canadian Medical Association (CMA) strategic 2020 plan commits to promoting patient-centered perspectives to influence practice and engage patients and physicians in approaching care. The consensus on the value of the PCC framework within Canada justifies further why it is fitting for analyzing gamete donor reimbursement policies.

The goals of these reviews were to support consistency between PCC and the ethics of care and to justify PCC as the theoretical framework for analyzing gamete donor reimbursement policies. The ethics of care review generated a solid understanding of the ethics of care according to prominent scholars in the field. This was followed by a review of the PCC literature to gain an understanding of the currents state of the approach. The four major values identified in the literature were communication, care, relational autonomy, and upholding dignity. The literature review was instrumental to linking PCC to the ethics of care. The use of ethics of care also helped examine the PCC ethical framework more conceptually and identify major normative principles. The PCC model is a fitting framework to use in this ethical analysis of the proposed

policy because of the particular relational nature of reproductive health and the emotional aspects of reproductive medicine that call for a more patient-centered approach.

The remainder of this thesis will apply what was found in this literature review in the next portions of the thesis to ethically analyze Canadian proposals to policies regulating the reimbursement of gamete donors. The next chapter presents a systematic search and review to compile and qualitatively analyze the normative values of ethical review tools for health policy. The PCC values identified in this chapter will be used to deductively code these tools, which helped categorize them into the ethical theories they emulate through such normative values. The last portion of this thesis uses the PCC principles found in this chapter to assess the alignment of the proposed policies to reimbursing gamete donors to the PCC framework.

Chapter 3: Identifying and classifying tools for health policy ethics review: A systematic search and review

Preface and Contributions of Authors

"Chapter 3: Identifying and classifying tools for health policy ethics review: A systematic search and review" constitutes a manuscript prepared with the intention to publish in a public health journal with Canadian readership. This manuscript was prepared by following the methodology identified by Grant and Booth (2009) for a systematic search and review, and by consulting the PRISMA checklist for literature reviews while preparing a protocol. The authors and their contributions are listed below.

Authors

Mary Henein, B.Sc., was the first author on this manuscript. She prepared the protocol, conducted the literature search and screening, conducted the qualitative analysis and description, interpreted the results, and prepared the manuscript.

Carolyn Ells, PhD, was the supervising author on this manuscript. She contributed to revising the protocol, served as the second reviewer for the literature search and screening, reviewed the qualitative analysis and description, contributed to interpretation of results, and assisted with preparing the manuscript.

Abstract

Context: Ethical review and analysis of health policy may help to ensure policies address the needs of society and align with relevant values and principles. Institutional health policy analysis present difficulties, such as the informality of analysis and the clarity of ethics focus. This suggests a growing need for tools to guide and conduct ethical reviews of existing and developing policies at the institutional and government levels.

Objective: To identify the ethical values and theory that influence health policy ethics review tools and their applicable scope.

Design: A systematic search and review of the academic and grey literature was conducted to compile existing tools designed for health policy ethics review. Academic sources searched were Pubmed, SCOPUS, Cochrane library, BELIT, ETHXWeb, and EMBASE. Grey literature was searched using ProQuest, handsearching relevant articles and journals, and Canadian and Australian government websites. Included articles were eligible if they were a step-by-step tool, designed to review existing or proposed health policy, and had strong ethics focus. Literature was excluded if it did not meet the inclusion criteria, was designed for research ethics review or was a decision tool for clinical encounters. Literature was limited to English and French. The extracted data was synthesized using qualitative content analysis. The tools were organized into three major qualitative categories: ethical values or principles, ethical theories, and scope. The structures of the tool's steps were qualitatively described.

Results: The search yielded 13 health policy ethical review tools. Qualitative content analysis revealed that all of the tools were influenced by multiple ethical values and that a majority were influenced by than one ethical theory. The most common values were non-maleficence and beneficence (92.3%). The most common influencing ethical theory was the Principle approach

(92.3%). A unique category was the value of justice because it was found to be a value as well as a theoretical framework in the tools. The tools varied in their applicability to government and institutional health policy and adopted various sequential structures, which included guiding questions to fulfilling specified ethical obligations.

Conclusions: This review aimed to systematically search for the available tools and critically review their ethical bases. Most tools assess how a policy benefits the health of the target population, reduces health burdens and inequalities, and constrains or promotes individual autonomy. The structure of the tools demonstrates a heterogeneity of methodology designs to approach policy ethics review. This research offers a unique contribution to the bioethics field that provides a useful resource and understanding of the current ethical review tools for health policy.

Introduction

Public health actions, including implementation of policies or regulations governing health, are often supported by ethical judgements (Kenny & Giacomini, 2005). These actions reflect what public society deems should be valued (Childress & Bernheim, 2008). The field of healthcare policy and public health is increasingly facing more complicated ethical concerns and actions with moral consequences (Bernheim, Nieburg, & Bonnie, 2007). While health policy has become focused on scientific evidence, it is situated within a broader social construct that fundamentally assumes philosophical and moral implications (Ansell & Geyer, 2017).

Health policies need ethical analysis to ensure it not only addresses the needs of society and is effective, but to also ensure it is ethically justified according to important ethical values and principles (A. Frolic et al., 2012; Funk & Freeman, 2011). Specifically, Hospital Ethics Committees have often been tasked with reviewing health policy and assisting in the development of policies within their institutions (Carolyn Ells, 2006; Flamm, Hester, & Schonfeld, 2012; A. Frolic et al., 2012). Moreover, governments are expected to ensure their policies achieve their intended goals (Funk & Freeman, 2011) and some argue that they should have targeted ethical review for their policies (Kenny, Melnychuk, & Asada, 2006).

Despite these authors' explanations, health policy and public health ethics have not traditionally been afforded equal, distinct attention similar to clinical ethics and bioethics. As a result, public health professionals have navigated ethical issues with the same ethical expectations as these fields (Baum et al., 2007; Kass, 2001). Since public health puts an "emphasis on population health rather than issues on individual health" (Baum et al., 2007, p. 657), it can be difficult to balance individual liberties traditionally valued in clinical ethics and public good when enacting public health policy (Petrini, 2010). Kass (2001) indicates that the result of applying clinical ethics frameworks in public health is the justification of "exceptions"

to these norms in the name of public safety and health (p. 1777). Seavey, McGrath, and Aytur (2014) also acknowledge the difficulty to construct policy that satisfies both individual and societal ends. In Canada, concern was notably voiced in a CIHR Funded "Think Tank" in 2003 regarding "why public health has not received attention from decision-makers" (Frank, Di Ruggiero, & Moloughney, 2003, p. 8). Kenny et al. (2006) argued that an important element to implementing a robust Canadian public health system was a "meaningful ethic of public health" (p. 402), but that this was neglected at the time.

While it remains a relatively new field (Abbasi et al., 2018), more researchers and bioethicists recognized the need for specific ethical frameworks for public health applications. Kenny et al. (2006) and Baum et al. (2007) argue that health policy and public health ethics are distinct from clinical ethics, requiring ethical consideration "tailored to a public health approach" (Baum et al. 2007, p. 659). Childress and Bernheim (2008) and Bernheim et al. (2007) claim that public health involves collective efforts to improve health, which would benefit from addressing the conflicts between certain principles by using "…a principled and also process-oriented framework for addressing ethical dilemmas that sometimes arise around public health" (Childress & Bernheim, 2008, p. 159). These efforts towards isolating issues within public health ethics indicate a growing understanding of its importance within the broader field of medical ethics and philosophy.

Despite the growing attention given to public health ethics and policy ethics, ethical review and consistency are lacking in Canadian health policy. This is evidenced by a systematic review published in 2009 that found Canadian government healthcare policies specify ethical principles or values in their description, but lacked consistency in definitions, explicit accomplishment within the policy, and broad agreement of values within similar disciplines (Giacomini et al.,

2009). A. N. Frolic, Drolet, and Group (2013) present similar challenges within institutional health policy analysis, including the informality of analysis and the clarity of ethics focus. This reality may contribute to a lack of systematic consensus about a structure for ethical analysis of health policy. Bernheim et al. (2007) suggest that "public health ethics is less formal and involves exploring society's values and justifications for collective public health decisions when law is not determinant" (p. 111).

Ethical review and analysis may provide the means to filling the apparent gap in the consistency and comprehensiveness of health policy. A brief literature search revealed two literature reviews that summarized public health ethics frameworks (Abbasi et al., 2018; Have, 2010). These reviews included all tools, frameworks, and moral values that were prevalent in public health ethics, regardless of whether they were sequentially structured tools. Recognizing that the ethical review of health policy remains challenging in Canadian health policy and attention to public health ethics continues to be limited (A. Frolic et al., 2012), we reasoned that tools that are structured with explicit, sequential steps, would be attractive for those seeking a tool for review of health policy from an ethics perspective.

The primary aim of the review presented in this chapter was to assist with the overall goal of this thesis, which is to analyze the ethical considerations and permissibility of the new Canadian policy governing reimbursement of gamete donors. In addition to the necessity of this review for the present thesis research, this review aimed to contribute to the broader literature on health policy and public health ethics. The research here aims to compile a list of existing tools in order to provide a resource of what sequential tools that have been developed thus far.

Objectives

The objective of this review was to compile and summarize tools with sequential steps that are available for ethical review of health policy and analyze their focus and priorities. The questions that this review aimed to answer were:

1. What health policy ethical review tools are available?
2. What are the main priorities and steps of analyses in tools guiding the ethical review of health policy?

Methods

Literature Review Approach

In order to compile the health policy ethics review tools, a systematic literature search and review was conducted according to Grant and Booth (2009), who explain that a systematic search and review "combines the strengths of a critical review with a comprehensive search process" (p. 102). This approach was chosen for answering the research question because it allows the search to encompass resources not limited to academic sources. Useful tools that met the criteria were expected to be found in the grey literature, such as government or health organization websites. In order to collect these tools, a comprehensive search was needed. The review method benefits from a critical review approach, where the articles or tools were critically evaluated for quality and inclusion. Since the definition of "tool" or "framework" is broader than what was intended for inclusion here, it is important that each tool was critically examined for the purposes of answering the specific research question. A traditional systematic review could not accommodate for these critical assessments or various materials, while a rapid review may not have been comprehensive enough. Therefore, using a method that incorporates two useful approaches was deemed the most suitable method to answer the research question.

Eligibility Criteria

The inclusion criteria were as follows:

1. Empirical research (quantitative, qualitative, or mixed methods). This is to uncover academic, empirical research that was used to develop a tool for the purpose of health policy ethics review.
2. Conceptual or literature research (non-empirical). There are significant resources in bioethics that are not empirical research. These materials are included in order to capture tools that arose not from empirical research but were developed from philosophical and moral theory to apply to health policy ethics review.
3. Developed by an institution/agency. This is included because institutions or governments may develop their own tools for the purpose of health policy ethics review, and these would not be academic resources. However, they may be useful for reviewing health policy and should be included in this review.
4. Step-by-step/sequential tool/instrument guiding ethical review of health policy. The research aim in this thesis is to use a tool that is structured by steps and not simply a list of moral principles to consider. This feature is expected to formalize the health review process and make it more accessible to professionals who undertake health policy ethics review. Therefore, the materials included in this review need to be a tool that has explicit steps to perform an ethics review.
5. Developed specifically for reviewing health policy- the material needs to explicitly state this as an application. This criterion helps to exclude materials that are for clinical decision making or policy development rather than review. Since the purpose of this research is to conducts an ethics review a health policy, the tools need to be targeted to this application.

6. Strong focus on ethical analysis/review. Since this thesis is a healthcare policy ethics review, the tool should have indication that it is focused on reviewing or analyzing the ethical implications or considerations of a policy.
7. Designed for government or institutional level. This is to ensure materials that have tools designed for both levels of policy are included, as they are both pertinent to the research aim.

The exclusion criteria were:

1. Frameworks that are not sequential or step-by-step, thereby not meeting the eligibility criteria.
2. Documents that outline tools for research ethics review. This is not the same as health policy ethics review and would not be applicable to the research aims of this chapter or of the thesis in general.
3. For policies that do not relate directly to healthcare (i.e. environment, education). This is to ensure specific concerns related to healthcare are reviewed using the tool, rather than other unrelated policy concerns.
4. Are not able to be applied to reviewing the ethics of the existing or proposed health policy. If the tool does not specifically indicate that it can be used for reviewing existing or proposed healthcare policy, then it may not be the purpose of the tool and thus should not be included in the review.
5. Decision making tools for clinical encounters. The research objectives are specific to healthcare policy ethics review, therefore tools made for clinical encounters are not relevant and are to be excluded.

The limitations were the literature must be in English or French in order to be inclusive to Canadian literature. Literature was not limited by year because it was important for the research goal to determine the state of the field, including tools from earlier years as well as recent.

Search Strategy

Academic and grey literature sources were searched. Two university librarians were consulted during preparation of the search strategy and following the search to ensure the search was comprehensive[8]. The academic literature was searched using the following databases: PubMed, EMBASE, Scopus, Cochrane, and ETHXWEB. Following this initial search, specific academic journals that were suspected to contain relevant articles were individually searched: *Canadian Journal of Public Health*, *Hospital Ethics Committee (HEC) Forum*, and *Health Policy*. These journals either publish on the topic of healthcare policy or came up during the database search, which justified handsearching them to ensure no materials were missed. Articles were cross-referenced if the references appeared to meet the eligibility criteria. The cross-referenced materials were Bellefleur and Keeling (2018), Frolic et. al A. N. Frolic et al. (2013), Haynes, Palermo, and Reidlinger (2016), Cohen (2016), and Marckmann, Schmidt, Sofaer, and Strech (2015).

The grey literature was searched using the following website platforms: WHO European Centre for health policy, Institut national de sante publique, ProQuest Dissertation and Thesis Global, Alberta Health Network, CIHR, PEI Health, and The Australian Government Department of Health.

The Boolean approach was used to search academic databases (Table 3). MeSH terms that were used were "Ethics committees, clinical", "Health policy", and "Guidelines as topics." The terms were chosen in order to narrow the results as much as possible to ethical review tools that present a sequence of steps and are specific for reviewing health policy. Each term has synonyms which are presented in the columns of Table 3, and the different concepts are

[8] One librarian specialized in family medicine and the other specialized in social sciences of medicine and history of medicine.

presented in the rows. The concepts pertain to ethics, reviewing, health policy, and sequential tools. The different synonyms were meant to capture tools that used different terminology but presented a tool that may be included. "Hospital Ethic Committees" was included as a term because it could include materials that described the work of hospital ethic committees, which include reviewing healthcare policy as a mandate. The search terms “moral” and “instrument” were derived after a few materials were found with varying terminology. Search terms used in the grey literature were derived from the concepts in the Boolean approach but modified for use in the simpler search function of the particular websites.

Table 3: Boolean search strategy

Terms in the rows are the concepts, which are entered into the search with an AND. Terms in the columns are synonyms and are added to the search with an OR.

Health policy (MeSH)	AND	Review	Tool	Ethics
OR		OR	OR	OR
Healthcare Policy		Analysis	instrument	Ethical
			Stepwise tool	Moral
			framework	Hospital Ethic Committees (MeSH)
			Guidelines tool	Ethics committees, clinical (MeSH)

Selection Process

Articles were screened by title, abstract, and full text by M.H. First, the title of each document from the search results were screened. If it described the development or use of an ethical review tool for health policy, or some variation of this according to the search terms, the article was saved. Then, the abstract was screened to determine if the article met the specific eligibility criteria. Articles that met the eligibility according to the abstract were put in a separate location and screened for final inclusion by reading in detail. Articles that met the full inclusion

criteria were placed in a separate folder to include in the review. C.E. reviewed M.H. final decisions by looking over the saved and included articles. Any discrepancies of included and excluded literature were discussed and resolved between M.H. and C.E. in person.

Data Extraction and Synthesis

The data was extracted independently by hand by M.H. The extracted data includes the author, the title of the tool and the items or steps the tool reviews. The author and name of the tool are summarized in Table 4.

A qualitative content analysis was used as the synthesis method for the review (Hsieh & Shannon, 2005). Qualitative content analysis reduces text to qualitative categories. This synthesis method is useful for this review because it allows each tool to be categorized by ethical theory embodied by the tool and the tool's ethical focus, priorities, or values. The tools can then be grouped into a category of scope, indicating the level of healthcare policy it was either designed for or implicitly applicable to. A coding scheme that represented categories was applied to the tools. The data was analyzed by reading the tool and highlighting text that represent ethical values, principles, theory, or focus, and was coded accordingly. The overarching code(s) applied to a tool were used to organize the tools based on the following categories:

1. Ethical theory/framework
2. Ethical focus/priorities
3. Scope (i.e. institution/organization, government)

The coding was deductive using the theoretical principles and values of the patient-centered care (PCC) from Chapter 1 analysis of PCC literature. Deductive analysis is an approach to qualitative research where "themes and explanations are derived primarily from a priori concepts" (Green & Thorogood, 2014, p. 205). This approach was chosen here to

determine an appropriate tool to use for reviewing gamete reimbursement policies from a patient-centered perspective. Also, we anticipated a utility in classifying the tools by ethical theory, as it would indicate to the user or reader what ethical approach was guiding the tool. Accordingly, we used existing concepts from PCC and moral philosophy to guide the analysis.

The structure of the tools was described by indicating how the tool was designed. The results from the qualitative analysis were tabulated (Tables 6-7) to determine the frequency of the values and theories that arose from the tools.

Results

Search Results

The search initially identified 2412 materials using the Boolean search strategy including academic and grey literature results. After screening these materials using the title and eligibility criteria, 76 articles were deemed potentially relevant to the search criteria and review goal. In order to screen these materials, the abstracts of all 76 articles were read to determine whether they met the eligibility. Based on the eligibility and exclusion criteria, 37 of the 76 screened articles were excluded from full-text assessment. The remaining 39 materials were read in detail and critically assessed to determine eligibility. Thirteen materials were considered to fit the inclusion criteria for the review, while 27 were critically determined to not meet all criteria or met exclusion criteria. The flowchart that illustrates the results from the search is represented in Figure 1.

Table 4 presents the names, author/developer, and date of publication of each ethics review tool that resulted from the search strategy and thus were included in the qualitative synthesis. For ease of analysis and reporting, the tools were assigned numbers 1-13, the order of their extraction. The assigned tool numbers are presented in Table 4 and used again in Table 5.

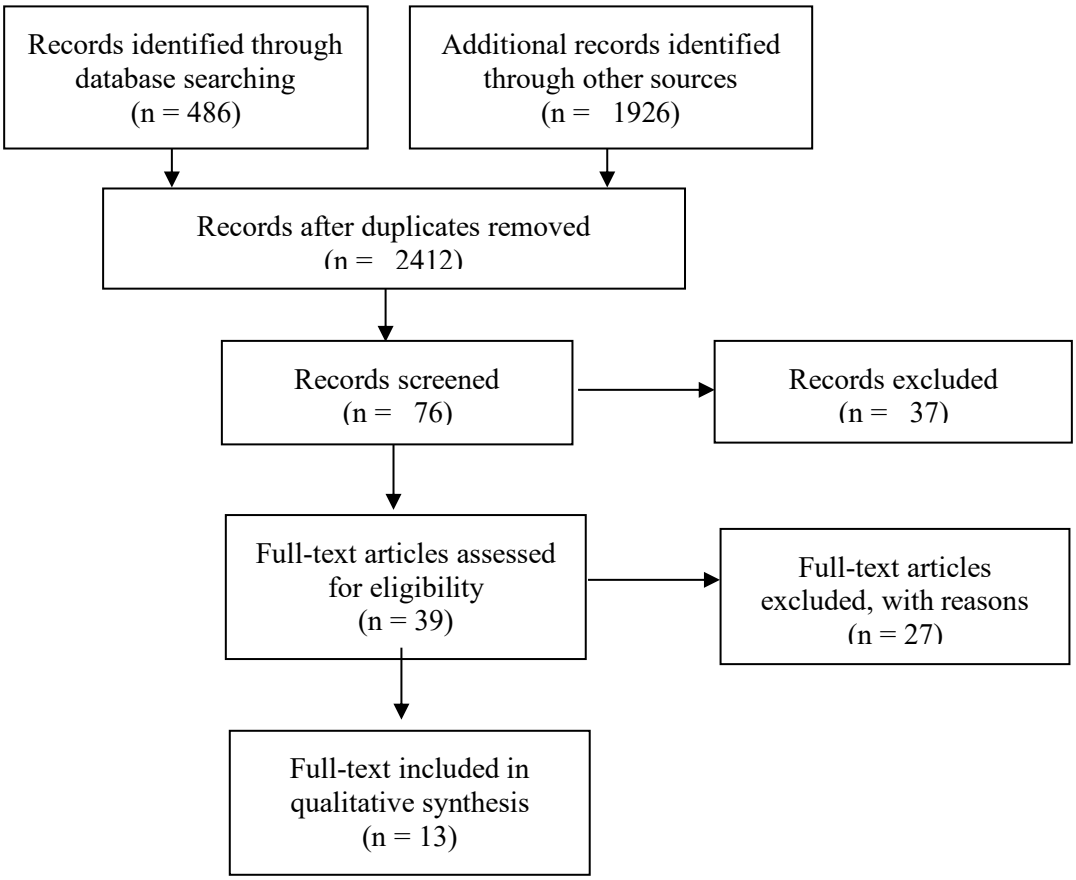

Figure 1: Flowchart of literature review results

Table 4: Articles Presenting Ethics Review Tools for Health Policy

Tool #	Tool name	Author/Developer and Date
1	IWK Question for Policy Review	McDonald, Simpson, and O'Brien (2008)
2	Core elements of Informed consent and Data sharing	Jamal et al. (2013)
3	AGREE Tool (Appraisal of Guidelines for Research and Evaluation of Evidence)	AGREE II Next Steps Consortium (2017)
4	NSHEN Policy Review Tool	Nova Scotia Health Ethics Network (2016)
5	ISSUES Guidelines for ethics policy review	Hamilton Health Science Group (2009)
6	Ethics framework for public health	Kass (2001)
7	Benchmarks of fairness	Daniels et al. (2000)
8	Policy Assessment Protocol based on social justice	Behrmann (2012)
9	Criteria for policy assessment	Cheung, Mirzaei, and Leeder (2010)
10	Strategy to analyze policies that are called paternalistic	Bellefleur and Keeling (2018)
11	Methodological approach for putting PHE into practice.	Marckmann et al. (2015)
12	Stewardship model	Nuffield Council on Bioethics (2014)
13	Ethics and the Practice of Public Health	Bernheim et al. (2007)

Qualitative Content Analysis

Qualitative content analysis was performed on the 13 tools by coding sentence-by-sentence. The sub-codes were grouped into categories of ethical theory, focus, and applicable level of healthcare policy (i.e. institutional/organizational or government). The sub-codes were grouped into categories of ethical theory, focuses/priorities, and scopes. After the coding, each tool was assigned to the categories that corresponded to the given sub-codes, which are listed under the columns "Ethical Theory/Framework" and "Ethical Focuses/Priorities" (Table 5). The structure of each tool was qualitatively described to indicate the review process of the tools and how the steps were designed to guide the review. The results from the qualitative analysis and description are organized in Table 5, corresponding to the assigned tool number for each tool.

Table 5: Results from qualitative content analysis of health policy ethics review tools

Tool #	**Ethical Theory/Framework**	**Ethical Focuses/ Priorities**	**Scope**	**Structure (descriptive)**
1	Patient-centered Principle approach	Communication, respecting autonomy, care, respecting dignity justice, Beneficence and non-maleficence	Institution	Ordered guiding questions
2	Patient-centered	Communication Respecting autonomy Respecting Dignity	Institution	Scoring the presence of particular sub-elements of a policy within overarching elements
3	Patient-centered Principle approach Virtue ethics Utilitarian	Communication, respecting autonomy, Scientific validity Beneficence, nonmaleficence, Distributive justice Honesty Utility Avoiding Conflict of Interest (Justice)	International and multi-use	Six domains with sub-criteria described

4	Principle approach PCC Deontology Utilitarian	Validity Beneficence, nonmaleficence, justice Communication, respecting dignity, Respecting autonomy Duties/maxims Utility Honesty	Universally applicable (p.2)	Steps to take during review along with guiding questions
5	Virtue Ethics Deontology Principle Approach Patient-centered Utilitarian	Discernment, honesty Duties/Maxims Social/distributive Justice, beneficence and nonmaleficence, Respecting dignity, communication, Utility	Institution	Sequential tasks each with sub-questions
6	Principle Approach Utilitarian Deontology Patient-centered Relativism	Beneficence, nonmaleficence Duty/maxims Justice (social, distributive, procedural) Respecting autonomy Utility Quality science/validity Respecting dignity, communication Pluralism/Relativism	Not Specified – "Public" policy i.e. government	Ordered reflective questions
7	Justice (Principle approach) Patient-centered Virtue Ethics Utilitarian	Distributive Justice, Social Justice Accountability Respecting Dignity, communication, respecting autonomy Nonmaleficence Utility Scientific validity	Government (developing countries specifically)	Benchmarks with ratings of the degree to which the policy achieves certain objectives
8	Principle approach Justice	Fairness, distributive justice, Beneficence, nonmaleficence Validity Respecting Autonomy	Institutional (meso level)	Sequence of criteria that must be met
9	Principle approach Justice Deontology	Communication Beneficence Scientific validity Distributive justice, Resource capacity Avoiding conflict of interest (justice)	Government	Sequence of criteria each with subsections that need to be met

		Duty based/maxims		
10	Principle Approach	Respecting Autonomy (i.e. addressing paternalism) Nonmaleficence Protectionism (weak paternalism, beneficence)	Government	Sequence of guiding, reflective questions
11	Principle Approach Utilitarian "Coherentist" or Relativism	Nonmaleficence, beneficence, justice, respecting autonomy Utility Reflection	Institution and Government	Sequence of guiding questions
12	Principle Approach Patient-centered	Nonmaleficence Social Justice, beneficence, distributive justice, respecting autonomy Respecting dignity	Government	Ordered checklist of things the policy should/should not do
13	Utilitarianism Principle Approach Deontology Virtue Ethics Patient centered	Utility Respecting autonomy Justice Universality Nonmaleficence Duties/maxims Virtues Casuistry Communication	Government/ Institution	Steps of criteria with sub-questions

Results: Review Tools Ethical Priorities from Qualitative Analysis

Common values that were observed in the tools included nonmaleficence, beneficence, justice, scientific validity and evidence-based medicine, respect for autonomy, communication, transparency, and honesty (Table 5 and Table 6). Several of the tools prioritized that health policy must be evidence-based and have scientific validity. The proportion of tools that supported each ethical principles or values is tabulated in Table 6.

The majority of the tools prioritized how well policies focus on health outcomes, benefit the health society of society, and reduce disease and suffering (Table 6). Several of the tools (#3-7, #11, #13) explicitly address the presence of a clear policy goal(s) and that the policy goal(s) has an element of improving health in the target population. These tools also have criteria for

how well a policy is able to achieve its stated goal(s) and the type(s) of interventions or processes the policy indicates will most effectively achieve the stated goal(s).

Two tools (#6 and #10) prioritized the ability of the policy to be reflective and adjust the policy and normative values accordingly. The concept of reflection can be considered a relativistic approach, where reflection allows for new moral considerations to be deliberated on a recurring basis and for ethical judgements to be adjusted accordingly. Tool #10 calls this a "coherentist" approach, which "develops a coherent framework by specifying, testing, and revising [considered judgements]" (p. 2). A "coherentist" approach is flexible to changing principles as per the circumstances or as experience demonstrates is more appropriate.

There were several tools that identified justice as a priority of assessing health policy (Table 6). Further, these tools focus on ensuring the fair distribution of benefits and burdens, indicating a moral imperative of health policy to social justice. Some of the tools were explicitly designed with a framework of justice (#7 and #8). Some of the tools (#3 and #9) also recognize whether a policy either avoids or declares conflicts of interests.

The value of communication was seen in many of the tools (#1-7, #9, #13). This was presented through the tools in a multitude of ways. These included addressing the policy's dissemination of information, availability of information, methods of interacting with the public, and transparency of the policy goals.

Other criteria that were included in the tools were evaluation of a policy's impact on liberty, privacy, and how respectful a policy was of various patient aspects (#1-9, #10-12). Components assessed by the tools included how the policy interferes with a person's decision making, liberty, ensures proper informed consent, and protects privacy. The tools also assessed

whether a policy respects vulnerable populations, respects personal values, respect for rights, and whether the policy allows for respectful treatment of patients.

Table 6: Frequency and proportion of the values and priorities within the analyzed tools

Value	Frequency (# of tools, N= 13)	Proportion of Tools (%)
Nonmaleficence or beneficence or both	12	92.3
Respecting autonomy	11	84.6
Justice	11	84.6
Communication	9	69.2
Utility (efficiency)	7	53.8
Scientific validity/quality of evidence	6	46.2
Duty, maxims, or intent of policy	5	38.5

Results: Tools Underlying Ethics Theory or Theoretical Bases from Qualitative Analysis

The theoretical basis of each tool was not always explicitly included in the article that presented the tool. In such cases, they were determined by categorizing the values into specific underlying moral philosophies that encompass those particular values. In all cases, the values and principles that arose from the qualitative coding were analyzed for their origins in ethical theory in order to assess the (probable) broader level justification that each tool used for their assessment.

The tools reflected varied theoretical underpinnings in their assessment of health policy (Table 7). All of the tools except #10 and #2 presented more than one ethical underpinning that influenced their foci. On the contrary, #10 was entirely influenced by a principle approach to bioethics, prioritizing the principles of beneficence, nonmaleficence, and respect for autonomy. Tool #2 was patient-centered focused, prioritizing respect for dignity, respecting autonomy, and communication.

The Principle approach, utilitarian, and PCC were the most common influencing ethical theories (Table 7). Further, there was more than one tool (#7-9) that specifically used the justice principle as a broad theoretical assessment of health policy. Since there are multiple specific

principles of justice, these tools focused more precisely on a specific type of justice within the ethical policy analysis.

The other theories present in the tools were deontology and virtue ethics. These were less common than the three theories previously mentioned but were still present in more than one tool. Deontology was present in tools that assessed whether a policy had explicit health goals, duties, or maxims to the public health. Virtue ethics was reflected from tools that assessed the policy's honesty to the public and patients. It was also observed in policy tool that instructed the reviewer to discern the ethical issues that could arise from the policy.

Table 7: Frequency of the ethical theories that underlie the tools analyzed.

Theory	Frequency (# of tools, N=13)	Proportion of Tools (%)
Principle Approach	12	92.3%
Patient-centered	9	69.2%
Utilitarianism	7	53.8%
Deontology	5	38.4%
Justice	3	23.1%
Virtue Ethics	4	30.7%
Relativism	2	15.3%

Results: Review Tools' Applicable Scopes from Qualitative Analysis

The scope of the tools describes the level of policy they were designed for, either institution or government. The results from the qualitative analysis revealed various different scopes of application among the tools (Table 5). When unspecified in the tool or accompanying materials, other indicating phrases were used to determine the possible scope that the tool was implied for. These included phrases such as "public policy" and "international" indicating higher level policy in government, or phrases such as "universal" which imply they are applicable for meso and macro scopes of policy.

There were 5 tools with government scope (#6, 7, 9, 10, 12), 4 tools institutional scope (#1, 2, 5, 8), and 4 that were considered applicable to both (#3, 4, 11, 13), indicated in Table 5.

The tools that were theoretically influenced by justice were primarily tools designated for government scope, with only tool #8 designed for institutional policy. Six of the seven tools that were applicable to institutional policy had values consistent with the patient-centered framework, including 3 with both institutional and government scopes. The one institutional tool that did not classify as patient-centered embodied values more consistent with the Principle approach (tool #11). Utilitarian theory was seen in all 4 tools with both institutional and government scopes, but only 2 with government scope tools and 1 with institutional scope. Other ethical theories were not observed as more commonly present in a particular scope (Table 5).

Results: Review Tools' Structures from Qualitative Description

To be included in this review, the tools needed to have a sequential nature. This meant that the tools needed explicit steps or guided questions that were ordered to allow for usability by policy reviewers. Despite this shared feature, each tool presented such sequential structures differently (Table 5). Some structures were reflective questions about the policy and its implications, others were based on criteria or a checklist of ethical considerations. Some similarities were the use of steps with sub-questions or sub-items to review policy. Most of the tools posed questions about the policy under review rather than presenting a checklist of items a policy must have. A few tools used a checklist rather than questions.

Discussion

Bioethics, to date, has primarily focused on clinical and research activities and neglected the field of public health ethics (Kenny et al., 2006). Yet, public health and health policy are prominent fields in health and are directed by ethical assumptions (Bernheim et al., 2007; Childress & Bernheim, 2008). The moral features of public health and health policy create a need for a specific bioethical inquiry (A. Frolic et al., 2012; Have, 2010). Despite research in this

area increasing recently, it remains scarce in comparison to clinical and research ethics. There is still a need for attention in the area of bioethics of public health and health policy.

The research here takes a step in advancing public health and health policy ethics. Health policy may undergo ethical analysis or review, but the extent to which this analysis is systematic, standard, and consistent is unknown (A. Frolic et al., 2012). Hospital ethics committees (HECs) often conduct internal reviews of health policies in their institution, but this process is often informal and has not been well reported in the literature (A. Frolic et al., 2012). Ells (2006) identifies that "there may be no formal way to fit an ethics review of policies into an institution's policy development and review process" (p. 267), presenting a barrier for HECs to conduct comprehensive ethics review of health policies. It is also unclear whether government policies undergo ethical review, recalling that Giacomini et al. (2009) found that ethics was referred to, but not coherently incorporated into Canadian government health policies. Therefore, the use of a sequential and clear tool to undertake an ethics review of health policies may introduce formality into the review process.

The availability of such ethical review tools was unclear at the onset of this research. This research thus set out to compile and summarize available health policy ethical review tools with sequential steps, and to analyze their ethical foci and priorities. In order to accomplish this goal, a systematic search and review was conducted. In total, 13 ethical review tools for health policy were included. These tools were qualitatively analyzed and classified by their ethical priorities, theoretical basis, scope of applicability, and structure.

The overall findings of this project revealed a limited number of sequential tools that are available to conduct ethical reviews of health policy. The tools that do exist vary in their theoretical justification and ethical values and priorities. They also vary in their applicability,

scope, and step-wise structure. These differences may be due to the fact that some of the tools were developed to address a specific type of policy or a specific policy issue. For instance, tool #10 was specifically designed for paternalistic policy, tool #2 was designed for policies surrounding genomic data and data sharing, and #8 was designed for allergy health policy. This variance among the limited number of health policy ethical review tools found here may imply there is a need to develop standards for review tools used for healthcare policy, in order to systemize health policy ethics review.

A finding from this analysis was that scientific validity and the role of evidence is a key concern for ethical policy making. The focus on scientific validity is interesting because it positions moral truths as stemming from a positivist paradigm and worldview. Positivist epistemology assumes that "there is a stable reality 'out there'- that phenomena …exist whether we're looking at them or not, and that they exist in exactly the same way whether we understand them or not" (Green & Thorogood, 2014, p. 13). Assessing a policy's ethical permissibility by its scientific validity presents a position that aligns with positivism. Evaluating the morality of a policy by its scientific basis implies a normative assumption of the superiority of scientific truths over socially constructed truths stemming from paradigms such as constructivism (Green & Thorogood, 2014). Equating scientific validity and truths as moral truths seems to validate a positivist worldview and imply that a positivist worldview is an ethical worldview.

The promotion of scientific evidence as a moral criterion is supported by the evidence-based movement for healthcare policy, such as the claim by Donnelly et al. (2018) that "[a]n accurate, concise and unbiased synthesis of the available evidence is arguably one of the most valuable contributions a research community can offer decision- makers." However, others have criticized the exclusion of social values and principles when policy relies too heavily on

scientific evidence (Ansell & Geyer, 2017; Montori et al., 2013; Parker, 2017). Alternatively, it may be more valuable to support transparency of the rationale for healthcare policies, including the supporting scientific evidence but also principles, social values, and pragmatic considerations (Ansell & Geyer, 2017; Walton & Mengwasser, 2012).

There was a widespread focus on justice among the tools, suggesting an agreement that ethical health policy must impact their population fairly, both in terms of resource distribution and a health system's procedures. Yet, justice was conceived in different ways, namely as distributive, social, and procedural justice. Fairness was sometimes seen in conjunction with non-maleficence, addressing whether policies unfairly burden or harm certain populations. Further, utility and fairness were seen together in some tools. This pairing seemed to be an attempt to achieve a balance between two diverging obligations.

In addition to the focus on distributive, social, procedural, and non-maleficent justice, addressing conflicts of interests was interpreted here as an attempt to uphold justice. Conflicts of interests are present when an individual involved in the policy-making or enforcement has affiliations, financial or otherwise. These relationships have the potential to unduly influence decisions regarding said policy. Therefore, conflicts of interest can unfairly or inappropriately influence the policy and its mandate which violates the principle of justice.

Communication was a value that policy review tools addressed often. There were 9 tools that explicitly examined a policy's capacity to communicate key components of the policy such as the goals of the policy and the policy's accessibility in terms of language that is easy to understand. Communication is not only important in a clinical context between a provider and patient, but also in the larger health system structures that implement policies and programs. Epstein et al. (2010) support the value of communication in healthcare policy, particularly in

PCC, since it is "grounded in strong communication and trust…We argue that policy makers seeking to advance patient-centered care should focus on these metrics" (p. 1489). Patients should be able to understand the reasons, goals, and outcomes of the health policies that impact their population. In order to ensure effective and meaningful communication, these tools also address the transparency of a policy. Assessing how well a policy delivers its message effectively, transparently, and clearly demonstrates the moral value of communicating health policy actions to the public.

Respect for dignity and for autonomy were also values commonly incorporated into the tools (#1-9, #10-12). Respect for autonomy was more common than respect for dignity and is also a value that coincides with multiple theoretical positions. Tools that valued respect for autonomy were typically categorized into PCC and the four-principle approach, while respect for dignity was categorized into PCC. The relevance of these values for assessing health policy was interesting, given the scope of health policy as the population and not individual. The prevalence of these principles may demonstrate the goal of ensuring these values are not absolutely sacrificed for the promotion of public health.

Evidently, the four-principle approach continues to be influential in the field of bioethics, as a vast majority of the tools employ the values of this theory. The principles of "biomedical ethics", first proposed by Beauchamp and Childress in 1979, is now a seminal bioethical approach in the literature and in practice. While not unanimously agreed upon in the medical ethics community, the four-principle approach was proposed by its authors specifically for the field of medicine. Beauchamp and Childress (2013) base their biomedical ethics framework in the "common morality" (p. 2) as the universal morality, describing it as "…applicable to all persons in all places, and we rightly judge all human conduct by its standard." They assert that

respect for autonomy, justice, beneficence, and nonmaleficence, stem from the common morality. While these are not all of the principles that are valuable to biomedical ethics, they claim these principles are applied in a *prima facie* manner: they all are equally valuable but in particular circumstances, one may be more prevalent than others. The principles also are meant to serve as "…general guidelines for the formulation of more specific rules" (Beauchamp & Childress, 2013, p. 13). Consequently, the four-principle approach has garnered attention for its supposed universal application and usability to various circumstances in the fields of medicine and biomedical ethics.

If the principles of biomedical ethics are viewed as falling within a universal morality, they could be an appropriate guide for health policy ethics. Just as Beauchamp and Childress (2013) claim that their four principles can serve as general guidelines for developing particular rules, they affirm that "[m]oral principles and rules provide a normative structure for policy formation and evaluation…" (p. 10). Health policy can be considered specific rules governing health administration and delivery, and Beauchamp (1995) refers to health policy as "…a statement of general norms" (p. 183-184). If the four-principles truly arise from a common morality and are shared by society at large, as Beauchamp and Childress (2013) claim, then they may be useful tenets of right and wrong to guide public health policy and law.

The policy review tools primarily used the Principle approach by addressing a policy's impact on the fair distribution of benefits and harms (justice), the implied health benefits and reduction of harms (beneficence and nonmaleficence), and the appropriateness and impacts of a policy's limits on individual autonomy. The prevalence of this approach among the tools may imply that the influence of the four-principle approach in Western biomedical ethics reaches beyond micro-level interactions to meso and macro-level healthcare applications.

An interesting finding from this research was the overlapping and multiple theoretical bases of the tools. While some theories were more strongly influencing than others, values and priorities that stem from more than one theory were present in a majority of the tools. This may have happened because there are overlapping values between ethical theories, such as respecting autonomy as an important value in more than one ethical theory (four-principle approach, PCC). Further, the tools may use more than one ethical theory in order to balance the review of health policy. For example, the utility (efficiency) of a health policy is paramount concern for health policy but maximizing utility should not violate maxims or obligations that health officials have to the population. Reviewing policy from both utilitarian and deontology approaches allows policy reviewers to account for the diverse ethical considerations that may arise in health policy. In addition, this result may be due to the lack of a truly universal ethical theory that can account for the moral pluralism seen in our society and healthcare system. These reasons suggest why it may be advantageous to ethical review to be influenced by more than one ethical theory.

The structure of the tools may have an interesting influence on the processes of health policy ethics review. A common format among the tools was the use of reflective questions to motivate the reviewers to think critically about a given policy. Guiding questions allow reviewers the flexibility to review each policy based on unique features of that policy and health issue. As a consequence, each review would contain distinct moral considerations to the particular policy under review, rather than attempting to conform a policy to moral criteria that may not be relevant. Yet, there are still tools that assess a policy based on specific criteria, possibly giving the reviewers less liberty in their ethical analysis of the policy. The divergence of structure may introduce variability into the ethical deliberations of ethics review committees, thereby leading to less consistent review procedures among different institutions and

jurisdictions. Variability could potentially introduce inconsistency in reviews because health policies considered ethical in one institution could be reviewed as unethical in another, even if they serve comparable populations. Thus, while differing patterns of review may be acceptable as long as the review process is reported and follows a clear and justified protocol, the defense of a superior structure for application in public health could be necessary.

The defense of a specific tool structure in ethically reviewing health policy is not within the scope of this thesis, but such investigation would be valuable to the field of public health ethics. Considered in the abstract, tools that are structured as a sequence of specific criteria may guide specific reflection or may limit individual reflection due to their close-ended structure. Since public health is acclaimed as a practice of achieving societal goals through collective actions, which in practice often occur through state actions on behalf of a population (Baum et al., 2007; Dawson, 2011), it may be more appropriate for health policy to be ethically evaluated by meeting specific criteria without individualized reflection within institutions. However, health policy is vastly diverse, and one justified criterion in a particular context may not be relevant to all ethical considerations in all health policy contexts. A tool that employs sequential questions to guide health policy review may inspire internal reflection and individualized assessment of the policies adherence to unique norms or specific rules. In this latter case, deliberative questions that prompt ethical reflection of a health policy may be more appropriate to consider public health actions that have diverging moral implications for the target population.

Limitations

A limitation of this project was the ability to collect all of the review tools available. This review attempted to search the literature exhaustively and comprehensively. However, due to the nature of health policy, those reviewing the ethics of health policies may have own review

processes, which are not widely or academically available. Therefore, while several grey sources were searched, some tools may have been either missed or inaccessible to the author.

Another feature of this review that may be considered a limitation was the exclusion of some frameworks based on the critical nature of the review. The review tools selected were designed to follow an explicit step-by-step process of reviewing existing or proposed policies. As a result, some frameworks that provided general values to follow, or considerations with no intentional order, were excluded. The consequence of these exclusions could be the neglect of useful frameworks of moral norms to health policy or public health. Further, tools that were focused on the deliberation of public health issues were excluded based on whether they were applicable to the policy making process, not reviewing process. These may still be valued resources in health policy ethics that some may find useful for this purpose, but were excluded based on the research question of this review.

Conclusion

The research undertaken here is a unique contribution to the bioethics field that provides an understanding of the current state of health policy ethics. This research may provide knowledge users an avenue to more formal ethics review of health policy by providing a summary and analysis of the currently available tools specific for this purpose. Moreover, the results here reveal the current condition of health policy ethics review, which was elusive and unclear at the beginning of this project. Thus, this research has clarified the availability and theoretical underpinnings of ethical review tools for health policy.

The research here should motivate future inquiry into health policy ethical review in a few ways. Given the wide variation and limited number of health policy ethical review tools, and the dearth of broad endorsement for their use, this research should motivate a needs assessment and

an evaluation of the quality of the health policy review based on the use of these/such tools in practice. Attention should be paid to further developing tools to integrate the several values that these tools have shown as important to reviewing the ethics of health policy. This may include consolidating some of these tools with the goal to have a centralized, more robust approach to health policy ethics review. Drawing on this latter motivation, in chapter 4, this thesis will adapt and apply two tools that were identified in this review to address Canadian policy on reimbursing gamete donors (The Stewardship Approach and Analyzing Potentially Paternalistic Policies, displayed in Table 4). The use of these selected tools is anticipated to provide a strengthened ethical analysis of this policy by using two complementary structures and several ethical considerations that are relevant to dilemmas of reimbursing gamete donors. The approach taken will be further justified in the chapter.

The research in this chapter provides this thesis with a method to formally review the ethics of the proposed policy and contribute a practical example of effective ethics review of a health policy. This chapter is essential for next steps of this thesis by providing a list of tools specifically designed for ethics review of health policy. The analysis in this literature review specifically indicated the moral positions and values of each tool, which allows for a tool to be chosen to align with the theoretical framework of this thesis (PCC). Chapter four expands on Health Canada's proposed policy on reimbursing gamete donors and applies a patient-centered care framework as well as two tools chosen from this literature review to ethically review the proposed policy. The implications of the work here are that ethics review of health policy can be made more accessible, formal, and transparent through the use of a tool exclusively designed for health policy ethics review.

References

Abbasi, M., Majdzadeh, R., Zali, A., Karimi, A., & Akrami, F. (2018). The evolution of public health ethics frameworks: systematic review of moral values and norms in public health policy. *Med Health Care Philos, 21*(3), 387-402. doi:10.1007/s11019-017-9813-y

AGREE Collaboration. (2003). Development and validation of an international appraisal instruemnt for assessing the quality of clinical practice guidelines: The AGREE project. *Qual Saf Health Care, 12,* 18-23.

AGREE II Next Steps Consortium. (2017). The AGREE II Instrument. Retrieved from: http://www.agreetrust.org

Ansell, C., & Geyer, R. (2017). 'Pragmatic complexity' a new foundation for moving beyond 'evidence-based policy making'? *Policy Studies, 38*(2), 149-167. doi:10.1080/01442872.2016.1219033

Baum, N., Gollust, S., Goold, S., & Jacobson, P. (2007). Looking Ahead: Addressing ethical challenges in public health. *Journal of Law, Ethics, and Policy, Symposium,* 657-667.

Beauchamp, T. L. (1995). Principlism and Its Alleged Competitors. *Kennedy Institute of Ethics Journal, 5*(3), 181-198. doi:10.1353/ken.0.0111

Beauchamp, T. L., & Childress, J. F. (2013). *Principles of Biomedical Ethics* (7 ed.). New York, NY: Oxford University Press.

Behrmann, J. (2012). *Ethics in Health Policy for Allergy: A Practical Approach for Decision-Makers.* (Doctoral Dissertation), Université de Montréal, Montreal, Quebec, Canada.

Bellefleur, O. and Keeling, M. (2018). *How Can We (and Why Should We) Analyze the Ethics of Paternalistic Policies in Public Health?* Montréal, Québec: National Collaborating Centre for Healthy Public Policy.

Bernheim, R. G., Nieburg, P., & Bonnie, R. J. (2007). Ethics and the Practice of Public Health. In Hoffman,R.,Goodman, R., Lopez, W., Matthews, G., Foster, K., Rothstein M. (Ed.), *Law in Public Health Practice.* (pp. 110-135): Oxford Scholarship Online.

Chalmers, I. (2005). If evidence-informed policy works in practice, does it matter if it doesn't work in theory? *The Policy Press, 1*, 227-242.

Cheung, K. K., Mirzaei, M., & Leeder, S. (2010). Health policy analysis: a tool to evaluate in policy documents the alignment between policy statements and intended outcomes. *Aust Health Rev, 34*(4), 405-413. doi:10.1071/AH09767

Childress, J. F., & Bernheim, R. G. (2008). Public health ethics. Public justification and public trust. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz, 51*(2), 158-163. doi:10.1007/s00103-008-0444-6

Daniels, N., Bryant, J., Castano, R., Dantes, O., Khan, K., & Pannarunthai, S. (2000). Benchmarks of Fairness for health care reform: A Policy tool for developing countries. *Bulletin of the World Health Organization, 78*(6), 740-750.

Dawson, A. (2011). Resetting the Parameters. In A. Dawson (Ed.) *Public health ethics: Key concepts and issues in policy and Practice (Cambridge medicine),* (pp. 1-19). Cambridge: Cambridge University Press.

Donnelly, C., Boyd, I., Campbell, P., Craig, C., Vallance, P., Walport, M., … Wormald, C. (2018). Four principles for evidence in policy making. *Nature, 558*, 361-363.

Ells, C. (2006). Healthcare Ethics Committees' Contribution to Review of Institutional Policy. *HEC Forum, 18*(3), 265-275. doi:10.1007/s10730-006-9011-4

Epstein, R. M., Fiscella, K., Lesser, C. S., & Stange, K. C. (2010). Why the nation needs a policy push on patient-centered health care. *Health Aff (Millwood), 29*(8), 1489-1495. doi:10.1377/hlthaff.2009.0888

Flamm, A. L. (2012). Developing effective ethics policy. In D. M. Hester & T. Schonfeld (Eds.), *Guidance for Healthcare Ethics Committees* (pp. 130-138). Cambridge, England: Cambridge University Press.

Frank, J., Di Ruggiero, E., & Moloughney, B. (2003). PROCEEDINGS OF THE "Think Tank on the Future of Public Health in Canada". *Canadian Journal of Public Health, 95*, 6-11.

Frolic, A., Drolet, K., Bryanton, K., Caron, C., Cupido, C., Flaherty, B., . . . McCall, L. (2012). Opening the black box of ethics policy work: evaluating a covert practice. *Am J Bioeth, 12*(11), 3-15. doi:10.1080/15265161.2012.719263

Frolic, A. N., Drolet, K., & Group, H. H. S. P. W. (2013). Ethics policy review: a case study in quality improvement. *J Med Ethics, 39*(2), 98-103. doi:10.1136/medethics-2011-100461

Funk, M., & Freeman, M. (2011). Framework and methodology for evaluating mental health policy and plans. *Int J Health Plann Manage, 26*(2), 134-157. doi:10.1002/hpm.1049

Giacomini, M., Kenny, N., & DeJean, D. (2009). Ethics frameworks in Canadian health policies: foundation, scaffolding, or window dressing? *Health Policy, 89*(1), 58-71. doi:10.1016/j.healthpol.2008.04.010

Grant, M. J., & Booth, A. (2009). A typology of reviews: an analysis of 14 review types and associated methodologies. *Health Info Libr J, 26*(2), 91-108. doi:10.1111/j.1471-1842.2009.00848.x

Green, J., & Thorogood, N. (2014). *Qualitative Methods for Health Research* (3 ed.). London, UK: SAGE.

Hamilton Health Sciences Clinical Ethics Committee on Policy Working Group. (2009). ISSUES: Guideline for Ethics Policy Review. Hamilton, ON, Canada. Retrieved from: https://jme-bmj-com.proxy3.library.mcgill.ca/content/medethics/suppl/2012/10/31/medethics-2011-100461.DC1/medethics-2011-100461supp_appendix1.pdf

Have, M. B., I.D.; Mackenbach, J.P.; and van der Heide, A. (2010). An overview of ethical frameworks in public health: Can they be supportive in the evaluation of programs to prevent overweight? *BMC Public Health, 10*(638), 1-11.

Haynes, E., Palermo, C., & Reidlinger, D. P. (2016). Modified Policy-Delphi study for exploring obesity prevention priorities. *BMJ Open, 6*(9), e011788, 1-8. doi:10.1136/bmjopen-2016-011788

Hsieh, H. F., & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qual Health Res, 15*(9), 1277-1288. doi:10.1177/1049732305276687

Jamal, S. M., Yu, J. H., Chong, J. X., Dent, K. M., Conta, J. H., Tabor, H. K., & Bamshad, M. J. (2013). Practices and policies of clinical exome sequencing providers: analysis and implications. *Am J Med Genet A, 161A*(5), 935-950. doi:10.1002/ajmg.a.35942 10.1002/j.1552-4833.2013.35942.x

Kass, N. (2001). An Ethics Framework for Public Health. *American Journal of Public Health, 91*(11), 1776-1782.

Kenny, N., & Giacomini, M. (2005). Wanted: a new ethics field for health policy analysis. *Health Care Anal, 13*(4), 247-260. doi:10.1007/s10728-005-8123-3

Kenny, N., Melnychuk, R., & Asada, Y. (2006). The Promise of Public Health: Ethical reflections. *Canadian Journal of Public Health, 97*(5), 402-404.

Marckmann, G., Schmidt, H., Sofaer, N., & Strech, D. (2015). Putting public health ethics into practice: a systematic framework. *Front Public Health, 3*, 1-8. doi:10.3389/fpubh.2015.00023

McDonald, F., Simpson, C., & O'Brien, F. (2008). Including organizational ethics in policy review processes in healthcare institutions: a view from Canada. *HEC Forum, 20*(2), 137-153. doi:10.1007/s10730-008-9067-4

Montori, V. M., Brito, J. P., & Murad, M. H. (2013). The optimal practice of evidence-based medicine: incorporating patient preferences in practice guidelines. *JAMA, 310*(23), 2503-2504. doi:10.1001/jama.2013.281422

Nova Scotia Health Ethics Network. (2016). *Ethics and Health Policy: The nuts and bolts*. Nova Scotia, Canada: Nova Scotia Health Ethics Network. Retrieved from http://www.nshen.ca/wp-content/uploads/2016/11/Ethics-and-Health-Policy-Nuts-and-Bolts-2016.pdf

Nuffield Council on Bioethics. (2014). *An Ethical Framework.* London, England: Nuffield Council on Bioethics. Retrieved from.http://nuffieldbioethics.org/wp-content/uploads/2014/07/Public-health-ethical-issues.pdf

Parker, L. (2017). Including values in evidence-based policy making for breast screening: An empirically grounded tool to assist expert decision makers. *Health Policy, 121*(7), 793-799. doi:10.1016/j.healthpol.2017.03.002

Petrini, C. (2010). Ethics-based public health policy? *Am J Public Health, 100*(2), 197-198. doi:10.2105/AJPH.2009.181511

Seavey, J., Aytur, S., & McGrath, R. (2014). *Health policy analysis: Framework and tools for success*. New York, NY: Springer Publishing Company.

Walton, M., & Mengwasser, E. (2012). An Ethical Evaluation of Evidence: A Stewardship Approach to Public Health Policy. *Public Health Ethics, 5*(1), 16-21. doi:10.1093/phe/phr037

Chapter 4: Do the Proposed Regulations for Reimbursing Gamete Donors Align with Patient-Centered Care Values? An Ethical Analysis and Review of the Health Canada's Proposed Policy

Preface and Contributions of Authors

"Do the Changes to Reimbursing Gamete Donors align with Patient-Centered Values? An Ethical Analysis and Review of the Health Canada's Proposed Policy" constitutes a manuscript prepared with the intention to publish in a health and law journal with Canadian readership. This manuscript was prepared by using the principles of patient-centered care indicated by the literature review for this thesis in chapter 1 to analyze the proposed regulations for reimbursing gamete donors in Canada. The authors and their contributions are listed below.

Authors

Mary Henein, B.Sc., was the first author on this manuscript. She analyzed the Health Canada documents of the proposed policy, interpreted these results, prepared the discussion and the manuscript.

Carolyn Ells, PhD, was the supervising author on this manuscript. She assisted in interpreting results of the analysis and revising the analysis and discussion.

Abstract

Context: The Assisted Human Reproduction Act (AHRA) criminally prohibits the purchase of human reproductive material and gametes in Canada. However, section 12 permits reimbursement of expenses related to the gamete donation in accordance with regulations. The absence of Health Canada (HC) regulation pertaining to this legislation has left gamete donation largely unregulated. In July 2017, HC released proposed section 12 policy.

Objective: To analyze the proposed policy for gamete donor reimbursement in Canada from a patient-centered care (PCC) framework.

Design: Following a review of the proposed regulations in section 12, an ethical analysis of the policy proposals was conducted using a PCC framework. The primary sources of data for reviewing the proposed policies were reports from HC, primarily "Towards a Strengthened Assisted Human Reproduction Act" and "What we heard: A summary of the consultation feedback from towards a strengthened assisted reproductive act". The analysis was approached by first addressing the regulations that HC proposed and then examining the proposed policies alignment with PCC.

Results: HC proposes to primarily regulate the types of expenses eligible for reimbursement and the documentation needed for reimbursement. Specifying eligible expenditures limits patients and does not promote their relational autonomy. Some of the included expenditures do uphold patient-centered values such as costs related to caring for dependants. Further, HC's initiative to seek stakeholder feedback allowed for communication and consideration of stakeholder perspectives, which is fundamental to upholding patient-centered care. However, HC's delayed development of these regulations violate patient-centered care values, since doing so left Canadian gamete donors vulnerable to exploitation in an unregulated gamete market.

Conclusion: The proposed regulations for section 12 move Canada towards better protection and care for those who altruistically donate their gametes to IPs. There is still room for improvement since these policies are restrictive to the unique experiences of gamete donors and IPs. Further, these policies lack pragmatic guidance on processing reimbursements and documentation. This analysis offers a PCC perspective on the ethics of the proposed section 12 regulatory framework.

Introduction

Purchasing gametes or reproductive material has been prohibited by the Assisted Human Reproduction Act (AHRA) section 7(3) since it was first passed in 2004. The law prohibits intended parents (IPs) or fertility clinics from paying gamete donors for eggs or sperm but does not penalize gamete donors for accepting payments. Upon conviction indictment, violating this law can be punishable up to 10 years in prison, a maximum $500 000 fine, or both ("Assisted Human Reproduction Act," 2004).

The AHRA prohibits reimbursing gamete donors without complying with regulations in section 12 or without receipt of expenditures, thereby permitting reimbursement for expenditures related to the donation. Section 12 indicates that the Governor of Council is responsible for developing regulations "respecting the reimbursement of expenditures for the purposes of subsection 12(1), including providing for the expenditures that may be reimbursed". Therefore, it is the Governor of Council's (i.e. HC) responsibility to develop and implement regulations on the reimbursement of expenditures to gamete donors.

In 2010, the Quebec attorney general challenged 32 provisions of the AHRA and won most of their constitutional challenges in the Supreme Court of Canada. ("Reference Re Assisted Human Reproduction Act," 2010). In 2012, Parliament amended the Act to comply with the rulings of the Supreme Court. The requirement for reimbursements to be made with an appropriate license was eliminated but the provision that requires recipients and agencies to follow reimbursement regulations in section 12 remained (Cameron & Gruben, 2011). Therefore, reimbursing gamete donors is still permitted in accordance with regulations in Canada.

The problems with reimbursing gamete donors in accordance with the Act is the lack of the regulations. At the time of writing[9], section 12 has not been put into force. While Quebec challenged the legitimacy of federal regulation of allowable expenses for gamete donation, the Supreme Court denied this challenge in part due to its relevance to section 7 (Downie & Baylis, 2013). Yet, no regulations were developed to regulate section 12. Without regulations, reimbursing gamete donors in accordance with the AHRA has become a legally ambiguous process (Cattapan, 2013; Nelson, 2013; D. Snow, Baylis, & Downie, 2015). The uncertainty and lack of clear guidelines have arguably been the driving force behind the underground reproductive market that has arisen in Canada (Downie & Baylis, 2013). Further, in the absence of regulations for section 12, the Act has not fulfilled its duty to protect those involved in AHR (D. Snow et al., 2015)

Health Canada (HC) released an overview of policy proposals regarding three sections of the AHRA, including section 12, in 2017. After a consultation period following their proposals, they released a second report summarizing the feedback they received (*Health Canada,*, 2018). These policies will provide parameters within which IPs and/or fertility agencies can reimburse a gamete donor for eligible expenses related to their donation in accordance with the regulations that are being developed by HC. Section 12 and the proposed policies relating to it have garnered serious attention among stakeholders and policymakers. Considering their importance, the proposals for gamete reimbursement policies compel a critical ethical analysis.

[9] HC is expected to release the policy in the Canadian Gazette II in early 2019, which would officially bring these regulations into force.

Chapter Objectives

Gamete donation policy has serious implications for donors and recipients, both of whom are patients[10]. As previously discussed, the potential for commercial gamete donation to foster exploitation, commodify human life, and not respect human dignity are central considerations for policymakers in reproductive medicine. The policies developed in response to these ethical concerns should aim to address these challenges. In addition, policy that governs gamete donor reimbursement should be ethically analyzed to ensure it does not inadvertently contribute to exploitation or disregard the dignity of gamete donors. The gamete donor reimbursement policy proposals may benefit from analysis from a PCC perspective, in alignment with Canada's adoption of a patient-centered care (PCC) framework for medical care. Recalling the defence for PCC as an ethical framework for reproductive health policy that was presented, PCC is also theoretically positioned to approach ethical issues that exist in the relational complexity of reproductive health. This chapter intends to analyze the alignment of the policy proposals by HC with the PCC ethical values that were identified in the literature review in chapter two: care, communication, respecting autonomy, and respecting dignity.

Methods

This chapter presents a critical ethical analysis of the policy proposals for section 12 of the AHRA by applying a PCC framework, followed by a health policy ethics review. The proposed policy was measured against the framework's values to address to what extent HC maintains the ethical standard of PCC. The data used for this research was the literature review that was conducted in this thesis in order to provide the ethical framework of PCC. The health

[10] It is understood that the children born from donated oocytes and sperm are also patients. However, for the purposes and scope of this thesis, which focuses on the transaction that occurs before an embryo is created and a child is born, this thesis will not focus its attention to the patient concerns of children born through donated gametes.

policy ethics review was conducted using two tools from the systematic search and review from Chapter 3. The documents "Towards a strengthened assisted reproductive act" and "What we heard: A summary of the consultation feedback from towards a strengthened assisted reproductive act" were used to provide information on HC's intended reforms for reimbursing gamete donors. Other useful sources of information were an HC consultation in Montreal in November 2018 and a "Best Brain's Exchange" report from HC.

The layout of this chapter is as follows. The section entitled Analysis I outlines the regulations that HC proposed in 2017 and the feedback they received on these proposals. These proposals are examined using the values of PCC in Analysis II. Finally, in Analysis III, two tools for ethical review of policy were adapted and applied to these proposed regulations.

Analysis I: An Overview of Proposed Regulation Surrounding Gamete Donor Reimbursement

An Overview of the Policy Proposals for Reimbursing Gamete Donors

In 2016, HC announced their intent to introduce the regulatory policy regarding reimbursing gamete donors and surrogates, alongside regulatory policies for two other sections of the AHRA. The introduction of a regulatory framework to the AHRA are a step towards improving the clarity and application of the AHRA in medical practice. The lack of regulation has lasted several years since the AHRA was passed in 2004 and the amendments in response to the 2010 Supreme Court decision. Without these regulations, gamete donation has occurred with minimal direction. Thus, a regulatory framework for the AHRA is an essential step towards caring for gamete donors in Canada.

In July 2017 HC released an outline of their regulatory reforms and policy proposals for the AHRA. This section will outline the relevant regulatory proposals made by HC in their 2017 publication, including their regulatory framework for gamete donor reimbursement (Section 12)

and their administrative and enforcement framework (sections 46-58) that impact the enforcement of section 12 (*Health Canada*, 2017).

The purpose of the regulatory framework, according to HC, is twofold. First, "the regulations will set out categories of expenditures that could reasonably be incurred by a donor or surrogate as a consequence of their donation or surrogacy" (p. 23). This gives HC the authority to limit the types of expenditures that donors may be reimbursed for. The second goal is to "specify a verifiable process by which reimbursements may be made" (p. 23). This would ensure that there is evidence of the transactions and that they comply with regulations.

As previously stated, section 12 bans reimbursement for gametes unless in accordance with regulations. HC has proposed that reimbursement should only be for "expenditures incurred in the course of sperm or ova donation, in the maintenance or transportation of an in vitro embryo" (p. 23). They further clarify that "Reimbursement must not involve monetary gain by involved parties, nor should it be a disguised form of payment or purchase" (p. 23). This distinction supports section 7, which prohibits purchasing gametes. The regulatory framework requires receipts for expenditures to prove that expenditures were indeed incurred for donation only and are not a form of payment.

HC controls what expenses are eligible for reimbursement in their regulatory policy. If an incurred expense is not on this list, it is not eligible for reimbursement. As a result, reimbursement for such costs would be a violation of the AHRA. This includes any expenses related to the donation that is not explicitly stated by HC as reimbursable. Therefore, reasonable expenses to be reimbursed are decided by the government, not by donor patients, IPs, or their physicians. Table 8 lists the expenditures that HC proposed as eligible for reimbursement to sperm and ova donors (*Health Canada*, 2017).

Table 8: Allowable Expenses for Reimbursement to Gamete Donors Proposed by HC

Eligible Expenditures
• Travel • Obtaining Medical Records • Health, Disability, or Life Insurance • Prescribed Products/Services • Drugs/Devices • Legal Services • Counselling Services • Care of Dependents

The final portion of the proposed policy refers to the process for reimbursement. HC proposed a "verifiable process by which reimbursements may be made" (p. 25). The requirements specified for this process are:

> "A declaration dated and signed by the person who requests reimbursement (i.e. the donor, the surrogate, or the person who maintained or transported an in vitro embryo); The receipt for each expenditure for which reimbursement is sought; and, If applicable, the written recommendation from a qualified medical practitioner" (p. 25).

HC instructs any person who issues a reimbursement to keep all the documentation described for at least 6 years following reimbursement. Therefore, HC specifies required documentation to reimburse a gamete donor, but they offer sparing information about who this documentation should be provided to and how this should occur.

The proposal report from HC included questions to stakeholders in order to prompt feedback on the proposals. Stakeholders were able to submit feedback via email, online, or mail. For the section 12 proposals, the question included to prompt feedback was:

1. "Please identify any other categories of expenditure that should be considered for reimbursement and explain why" (p. 24).

In summary, the main concern of HC for this section of the AHRA policy appears to be specifying what types of expenditures may be reimbursed to gamete donors and including those categories in their allowed reimbursements.

What they heard: HC Account of the Stakeholder Feedback

Following the release of "Towards a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals", HC held a 60-day consultation to hear feedback on the proposals from stakeholders and interested Canadians. They released a different document summarizing 57 comments that the department received in January 2018. The summary of the comments will be outlined here.

HC reports that the feedback that was generally positive on the movement towards more regulated reimbursement practices for gamete donors. They indicated that some stakeholders "suggested additional categories of expenditures for the [HC] to consider" (p. 4).

HC reports receiving opposing views from stakeholders on section 12. On one hand, some stakeholders supported a completely altruistic system, as they viewed any form of monetary gain by donors as a risk for exploitation of donors. Other stakeholders supported a model that allowed appropriate compensation. There was some criticism of a rigid system in which only specified expenses are reimbursable, as it is less adaptable to the unique circumstances that these transactions occur in.

There was also concern from stakeholders about the reimbursement of more general costs that are "'nontangible', such as time, effort, risk, and commitment" (p. 5). This concern relates to the problem of limiting reimbursement to a strict list of reimbursable expenses. Some stakeholders suggest a more generally worded reimbursement policy is preferable to allow for any reasonable expenses that are related to the donation.

Finally, HC says that stakeholders expressed a necessity for a mechanism in which complaints could be made to HC to "resolve compliance issues" (p. 5). In their initial proposals, their policy proposals for enforcement and administration are intended to handle complaints related to sections 8, 10, and 12 of the Act. Therefore, it is expected that such a complaint mechanism will fall into this regulatory policy.

Analysis II: The Proposed Policies Alignment with PCC Values

Due to the medically invasive nature of oocyte donation, gamete donation policy presents considerable patient concerns to women gamete donors (Gruben, 2013; Skoog Svanberg et al., 2013). Though to a lesser extent than oocyte donors, sperm donors are expected to participate in in-depth medical care before donation and should be treated as patients as well (Yee, 2009). There is empirical evidence demonstrating that the quality of medical care impacts the experience of gamete donation and may influence patients' decision to donate again (Kalfoglou & Gittelsohn, 2000). These considerations make it important to view gamete donors as patients receiving medical care, not reducing them to subjects, clients, or providers.

The proposed regulations for section 12 of the AHRA should align with PCC values for at least two reasons. First, the policies should be consistent with the position of Canadian medical associations, a majority of which support PCC within the medical practice (Canadian Medical Association, 2018; BC Ministry of Health, 2015; World Health Organization, 2007). Since Canadian medical practice is embracing a patient-centered approach as a standard, gamete donation processes should not be exempt from that standard. Second, the Commission on New Reproductive Technologies final report claimed that their conclusions were based on the theory

of ethics of care[11]. As already explored, the principles of ethics of care are congruent with PCC. This position provides a fitting framework to approach an ethical evaluation of HCs proposed regulatory approach to gamete donor reimbursement. The values of PCC from the literature review in this thesis were: respect for relational autonomy, respecting patient dignity, care, and communication. The sections that follow will assess the proposed changes with respect to these values.

Communication

Communication supports the establishment of trust and a relationship between care providers and patients. It should be consistently fostered and valued in all patient-provider interactions, including those with gamete donors and IPs. According to a qualitative study, communication and PCC is important for the donation experience (Kalfoglou & Gittelsohn, 2000). Specifically, the depersonalization of donors was reported as a negative experience for oocyte donation. Yet, a longitudinal study found gamete donors were not always communicated enough information about the donation process and consequences (Skoog Svanberg et al., 2013). It is important for the reimbursement regulatory framework to ensure it does not hinder patient and provider communication, but rather promotes it between the involved stakeholders.

One goal of the regulations surrounding section 12 is to "provide clarity and structure to the reimbursement process for stakeholders" (p. 23), primarily by specifying a verifiable process to reimburse donors. By aiming to achieve clarity in the reimbursement process, HC appears to

[11] Ariss (1996) argues why the Baird report was not truly based on an ethic of care. This thesis is primarily concerned with the policy proposals alignment with patient centered care (which as previous chapters indicate, are congruent with the goals of ethics of care) but understands that the Baird report itself may not align well with its intended theoretical framework.

value communicating with stakeholders to some degree. However, it is more important to address how HC attempts to operationalize communication rather than assess their stated objective.

Essentially, HC aims to achieve communication between providers, IPs, and donors by using documented evidence such as receipts, declarations, and written statements by health practitioners. Besides these requirements, there are no clear ways that HC specifies to ensure clarity or communication between health care practitioners, donors, IPs, and HC. Since communication in the patient-centered framework is meant to engage patients and to allow them to be active participants in their medical care, the proposals for the regulatory framework fall short of truly upholding communication in the patient-centered sense. In reality, the proposals aim to ensure that patients (that is, IPs and donors) understand the rules and parameters of the reimbursement regulations that are set out by HC.

The proposals focus more on verification rather than enhancing meaningful communication. The requirements for reimbursement are types of proof of legal transactions: that the donors requested a reimbursement, receipts for expenses that are reimbursable, and physician-warranted documentation for expenditures without receipts. Therefore, these proposals aim to ensure compliance with regulations and ensure no illegal reimbursement or payment is occurring for gamete donation. While it is important for HC to ensure the Act is not being violated, the proposals do not promote communication to enable and support PCC. In contrast, the "clarity" is provided by HC in the form of instructions for donors and IPs to follow when making reimbursements.

An important step HC took towards effective communication was to ask for stakeholder feedback, which in itself allowed for the possibility of meaningful communication. HC also

offered more than one method to submit feedback, such as mail, online, or email. While this process is not a part of their proposals, the feedback is meant to be considered in developing the proposals and results in patient engagement with the policies. As such, HC upholds communication between the Department, patients, and other stakeholders.

Respecting Relational Autonomy

There are significant concerns about how well the AHRA upholds patient autonomy and specifically the sections related to compensation and reimbursement to gamete donors and surrogates. Cameron and Gruben (2011) argue that reproductive autonomy was largely ignored during the litigation surrounding the Quebec challenge of the AHRA by both the provincial and federal governments. They continue to point out how limiting the ability for compensation to gamete donors restricts reproductive autonomy. Respecting autonomy, specifically relational autonomy needs consideration since it is an important concern for reimbursing gamete donors and for upholding PCC values.

Limiting the specific eligible expenditures for reimbursement is inconsistent with obligations for respecting relational autonomy. In the context of PCC, relational autonomy involves respecting patients' inherent claims in determining their own life goals (Epstein et al., 2010; Hammell, 2013). The "relational" aspect positions autonomy not as an egocentric ideal but is finely tuned to people's lived experiences, which includes considering valuable relationships and viewing decisions within a relational framework (C. Ells et al., 2011). Restricting patients from determining reasonable expenses to request, or for IPs to commit to reimbursing, does not fully appreciate the unique situations from which they enter donation agreements. Even if the prohibition on financial gain for donation is acceptable, a patient's donation may require unanticipated and unique expenses from which they may have legitimate claims to

reimbursement. Limiting their ability to do so interferes with their ability to decide what reimbursements are relevant to their donation and for some this restriction may hinder their decision to donate.

The specification of eligible expenses by the government implies that patients themselves are incapable of deciding themselves what type of expenses are reasonable for reimbursement. Requiring receipted reimbursements of reasonable expenses in general and possibly suggesting what falls into this category of "reasonable" would be a more respectful mechanism to control gamete donor reimbursements. By limiting the interference to patients' freedom to decide what expenses are reasonable based on their lived experiences, relationships, and personal values, the policy would be more respectful to their autonomy and personal liberties. Public health policy is generally more concerned with collective goals, but restrictive policy should only be used when it is deemed necessary for population safety (Dawson, 2011). The restriction of reimbursements to specific expenses chosen by the government is viewed here as unnecessarily overriding donor autonomy, given that restricting patients to only reimbursing expenses is essentially avoiding commodification of human gametes.

Stakeholder feedback in the HC consultation also identified that having a list of eligible expenditures could be problematic. The feedback indicates that "a definitive itemized list of reimbursable expenses could be too rigid to account for the individual circumstances of each donation and surrogacy arrangement" (p. 5). Relational autonomy requires a commitment to understanding people within their own contexts and to treat patients as whole persons with unique interests. It is not respectful to patient autonomy to bar them from deciding for themselves which expenses are required for them to donate. If PCC should be upheld within the parameters of reimbursing gamete donors for expenses, patients should be treated as capable to

determine what expenses are reasonable and related to their donation. Thus, amending the limited reimbursement categories would be a step towards respecting relational patient autonomy.

Care

A pillar in PCC is the value of care. Within the ethics of care theory, care is described as valuing caring responsibilities as morally valuable and useful for ethical considerations in public society (Carse, 1998; C. Gilligan, 1982). Care involves "taking care" of others, demonstrating compassion, and being attentive to those who bear vulnerabilities or show a need for specialized attention. In PCC, this was operationalized by demonstrating responsiveness to emotions, understanding patient reactions and patient fears, and promoting a "culture of care" (Santana et al., 2018, p. 433)[12]. Therefore, it is important to consider how well the proposed section 12 policies ensure and promote care for donors and IPs as patients.

HC exercises cautious care for patients by having the overall goal to prevent exploitation. This goal is explicit in the AHRA and the proposed regulations, given the prohibitions on paying for gametes in section 7 and the indication that reimbursements must not "disguise payment" or result in a financial gain by the donors. HC states that "the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition" (*Health Canada*, 2017, p. 5). The caution against exploitation demonstrates that HC aims to care because they are attempting to safeguard the wellbeing of others and those in vulnerable situations.

Canadian lawyers and bioethicists in this area have argued that the absence of regulations pertaining to reimbursement since the passing of the AHRA allows for exploitation and harms donors by fostering an unregulated gamete market (Cattapan, 2013; Downie & Baylis, 2013;

[12] For more comprehensive support of this definition of care in patient-centered care, see Chapter 1: Patient-Centered Care as a Theoretical Framework for Assisted Reproductive Policy.

Nelson, 2013). These authors suggest that the Canadian government was irresponsible for introducing the AHRA without the necessary accompanying regulations. It is possible that the mere introduction of the policy framework here demonstrates the value of care because it introduces the regulation needed to fully protect donors from exploitation and commodification.

However, the fact that these regulations have taken 14 years since the Royal Assent of the AHRA and 8 years from the Supreme Court ruling to be introduced by HC minimizes their meaningfulness. The lack of attention to the practices of gamete donation resulted in an underground market for gametes, specifically donor oocytes. This is both a violation of the value of care and the values the AHRA bases its provisions on. While the regulatory framework is now being developed, representing an attempt to abide by these values, it alone does not rectify their previous neglect. Implementing regulations is an important and required action, but it does not uphold care since HC has been inattentive to the needs of patients. Further, the needs of patients are now a result of the government's inaction. Thus, the policy proposals themselves may uphold care in some ways but the delayed response of HC to the need for specific reimbursement regulation does not espouse care.

Further, as the grey market flourished in the absence of a regulatory framework, it may now set a precedent for gamete purchase rather than altruistic donation. Motluk (2010) admits that while "Solid numbers would indeed be hard to obtain…but it takes only a couple of hours and a few phone calls to establish that purchasing eggs is a common practice for Canadians undergoing fertility treatment." With a paid gamete market already in place, IPs would potentially have to risk criminal penalty in order to obtain gametes in Canada or go abroad to pay donors (Downie & Baylis, 2013). The additional conflict that arises from the absence of

regulations is another instance of HC failing to uphold care for patients, in this case, care for IPs exposure to risk and to vulnerable situations in order to pursue AHR.

The policy embodies care by permitting reimbursement for care of dependents because it recognizes the care responsibilities of donors as valid. The inclusion of care costs for reimbursement demonstrates that HC acknowledges care as deserving of public attention and as a result, monetary reimbursement. Since there is no maximum amount listed in the policy, this demonstrates HC understands that there is no static value on care labour. As several ethics of care authors have noted, care labour has been devalued in public society and has historically been linked with systematic inequality and oppression (Tronto, 2013). The policy proposal here shows a recognition of the important value of care labour for gamete donors, who otherwise would be more disadvantaged from donating. Thus, this specific proposal aligns with the value of care in a PCC framework.

The exclusion of work-related expenses as eligible expenses for gamete donors, especially oocyte donors, undermines the value of care. Oocyte donation requires several appointments and medical procedures that would likely require appointments during working hours, leading to lost work wages (Gruben, 2013). Yet, only surrogates are proposed to be eligible to claim lost wages. Even sperm donors need to attend appointments during workdays and could lose work-related time and wages, though not to the same extent as oocyte donors. The exclusion of gamete donors in this respect does not ensure they are properly cared for over the course of their reimbursement since it leaves them unable to claim lost work wages as a reasonable expense of donation.

Despite some of the proposed regulations that value care in the new policies, there are more foundational gaps of care with the AHRA prohibition and limitation on compensation.

Scholars in this area have criticized the lack of attention to the inadequate care for gamete donors within the AHRA. Cattapan (2013) has pointed out that while the government aimed to protect donors from commodification by criminally prohibiting payment for gametes, they did not consider that exploitation can occur in the absence of payment. Gruben (2013) identifies how the resulting black or grey market for human gametes (especially eggs) has left women vulnerable to mistreatment (p. 253). Motluk (2010) reported that women in Canada have received upwards of $5000 for donating gametes by circumventing the system in a number of ways. The intent of prohibiting payments for donor gametes was to care for Canadian gamete donors, but care does not end with intentions but it also concerns the outcome (Edwards, 2011). Therefore, the incompleteness of the Act and the lack of enforcement were ways that HC did not fully apply the value of care when implementing the AHRA.

Respecting Dignity

The Canadian government has prohibited the commercial sale of gametes on the basis that it would violate human dignity to assign a monetary value to human body parts or tissue. However, "Parliament recognized that in order to promote an altruistic system, donors and surrogates should be permitted to be reimbursed for out-of-pocket expenditures incurred as a result of their donation or surrogacy" (p. 23). HC indicates that no person should financially benefit from donating their gametes. It is interpreted here that the underlying assumptions of these stipulations are that a financial benefit from donating is attributing market value directly to the gametes, which undermines human dignity. The Canadian government maintains its position that commercial gamete donor is unethical and exploits human reproductive capacities amid the proposed regulations.

Whether or not the claims made by the Canadian government are true to gamete donors experiences remains questionable. Despite the feedback to HC supporting this "expense neutral" reimbursement model, the empirical evidence on gamete donor experiences is sparse. One study reported that some donors had feelings of depersonalization and commodification when partaking in a paid donation in the United States (Kalfoglou & Gittelsohn, 2000). Some described it as feeling like "rent[ing] your body out" (p. 802). However, other studies have found that commercial oocyte donors had positive experiences (Bracewell-Milnes et al., 2016). Jordan, Belar, and Williams (2009) found that within the clinical and medical procedures, oocyte donors rated their interactions with clinical staff as the most positive aspect. However, it is difficult to determine if Canadian donors themselves feel less dignified if they are paid since the regulatory framework silences them from sharing experiences of commercial donation. Thus, it is still difficult to say whether or not commercial donors feel less dignified when paid as opposed to altruistic donation.

It is also unclear if the Canadian government's view of exploitation and commodification are reflected in public ethical attitudes towards payment of gamete donors. An American study on the public perception and opinions of financial compensation for gamete donors found that 90% of respondents believed in donor compensation for oocyte donors and 80% agreed with compensation for sperm donors (Lee, Farland, Missmer, & Ginsburg, 2017). The most common reason in support of oocyte donation compensation was the for medical risk (Lee et al., 2017). A minority responded that gametes have inherent value and deserve payment in return (30% for oocytes, 26% for sperm). This study suggests that the public may not perceive payment as pertaining to the gametes themselves but for the efforts of the donor and to compensate for their risk. While this is a study of American public views and does not represent Canadian values on

the subject, it suggests the possibility of financially compensating gamete donors without undermining human dignity. There are other studies that suggest altruistic donors do not agree with payment but agree with reimbursement (Bracewell-Milnes et al., 2016). Yet paid donors have been shown to support payment and not willing to donate without such payment (Bracewell-Milnes et al., 2016). It is not clear why they disagree but there is still a clear divide in the public perceptions of permissible compensation for gamete donors.

Before a policy is defended by obligations to respect human dignity, there should be an understanding of the meaning of dignity. However, defining a concept of human dignity itself is often overlooked even when it is used to defend particular actions. In the concrete sense, dignity itself comes from the Latin "dignus", which means "worthy". Human dignity then refers to the worth of humans or humanity. Moral philosopher Immanuel Kant's perspective of human dignity is as an inalienable feature of human beings that gives humans value only attributable to themselves. This moral value of a person is embodied in Kant's categorical imperative to "…the rational being himself, be never employed merely as means…that is in every case as an end likewise " (Kant & Abbott, 1873, p. 81). The inherent value that Kant assigned humanity defines human dignity as the worthiness of humans not because of the consequences of their actions, but because of an innate feature of humanity that is itself worthy.

Düwell (2017) reflects interestingly on the concept of human dignity within bioethics and how it is ill-fitted to the prominent, normative frameworks in the field. Unlike normative principles that are widely referred to and agree upon within bioethics, human dignity is not a concept with an assumed meaning. Modern bioethical issues have demonstrated divergence on understanding dignity as disagreements on defining humanity itself, whether humanity is unique in possessing dignity, and the physical manipulations that undermine human dignity have

become prominent. Bioethics may not possess, or at least does not apply, the methodologies that can embrace the complexity of human dignity within their frameworks.

A result from the ambiguity and abstract nature of human dignity, there has been disagreement on its usefulness in bioethics (Morrissey, 2016). A notable critic of the concept is Ruth Macklin, who charges human dignity as “a useless concept” in bioethics (Macklin, 2003). More specifically, the lack of defining it has shaped it into an “indeterminate concept” that does not move bioethical inquiries forward (Morrissey, 2016). The misuse of the concept of respect for human dignity can render it less meaningful in bioethical discussions and debates. Further, references to shallow conceptions of human dignity to justify health actions may lead to irresponsible decisions that do not, in fact, uphold such dignity. Consequently, it is paramount for health decisions and health policies that justify actions based on respect for human dignity need a sound and clear theoretical understanding of what human dignity is and how the decision respects that dignity. Otherwise, that justification is meaningless and diminishes any ethical value of human dignity.

The PCC literature is strongly positioned to value respecting dignity as a core obligation. In the PCC application, respect for dignity is expressed by the treatment of people as inherently valuable in and of themselves (World Health Organization, 2007). The Baird Report states that dignity implies that "All forms of human life (and indeed human tissue in general) should be treated with sensitivity and respect, not callousness or indifference” (Baird, Jantzen, McCutcheon, Knoppers, & Scorsone, 1993). PCC scholars often understand dignity as treating patients as people, not as simply the site of disease (Epstein et al., 2010). Their application of respect for human dignity recognizes how medicine has reduced people to diseases, thereby reducing them to objects to be treated. For the PCC framework, respect for dignity requires

rejecting this simplification of their patients in order to appreciate their inherent worthiness as human beings. Thus, respect for the dignity of patients is to embrace the moral imperative to treat all human beings respectfully and not objectively.

Human dignity, which is understood here as the recognition of "humanness" as undeniably worthy and such worthiness ethically obligates respect, is not violated by the proposed regulations. All of the eligible expenses address the process of reimbursement and do not reduce patients to a "gamete machine" or objectify their existence or their reproductive capabilities. The proposals are consistent with the Canadian government stance against commercialization, as they do not allow for any financial gain from participating in gamete donation.

The proposals further respect patient dignity during the course of their donation because permitting reimbursement of expenses is a way to respect donors as whole people, not simply gamete providers. Without any type of compensation, donors' dignity would be overlooked as they sacrifice their time, safety, and money in order to donate. Requiring them to do so would be reducing them to someone without their own interests and disregard their needs as patients and as individuals. Thus, implementing permissible parameters around the expenses that donors would have in order to donate recognizes them as inherently valuable persons whose needs should be met.

Despite the measures taken intended to protect the dignity of donors, the proposals do not have policies to amend exploitation that may occur within the reimbursement framework. The proposals introduce a mechanism for compliance through sections 46 to 58, which "authorize designated inspectors to verify compliance with any of the requirements of sections 8, 10, and 12". However, there are no indications of how complaints of non-compliance are to be made.

According to a consultation with HC, complaints can be made through the general HC website[13]. The proposals also do not address timelines for processing requests for reimbursements or how to ensure agreed upon reimbursements are made in a timely manner. HC indicated that this is not within the realm of the policies, as the policies only regulate what is reimbursable to gamete donors. A grievance process is important to the wellbeing of all those involved in third party reproductive practices, a view supported by other scholars (*CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act*). This gap disregards the possibilities of undermining the dignity of donors within the reimbursement model, similar to Cattapan's claims of the original AHRA (Cattapan, 2013).

Table 9: Summary of the policy proposals alignment with the principles and values of PCC

Principle	Aligned	Not Aligned/Missing
Communication	• Engagement with public/stakeholders on proposals • Informed about the reimbursement process	• Focus is on bureaucratic and compliance processes
Respecting [Relational] Autonomy	• Donation and reimbursement are permitted • IPs are not obligated to reimburse (IP autonomy)	• List of eligible expenses is limited and rigid
Care	• Reimbursement for "care for dependents" is permitted • Goal of preventing exploitation by prohibiting payment and reimbursement as "disguised payment"	• There was a delay in proposing and implementing policies • Work-related expenses are excluded
Respecting Dignity	• Reimbursements for donation-related expenses are permitted	• Complaint/grievance mechanisms are unclear

[13] This information was taken from a HC Consultation that M.H. attended on November 29th, 2018 in Montreal, Quebec. A search on their website finds a complaint mechanism for devices and products, but it is unclear if these activities would be appropriately reported using this mechanism.

Analysis III: An Ethical Review of the Proposed Policy for Reimbursing Gamete Donors

To conduct an ethical review of the policy proposals for reimbursing gamete donors, two tools identified from Chapter 3 will be used. The two tools chosen were the Stewardship model (*An Ethical Framework*, 2014) and the review tool for policies called paternalistic (Bellefleur & Keeling, 2018). The application of two tools allows two different review structures to be utilized, both having strengths that can be applied here. The Stewardship model has a list of criteria that public health policies should meet, and the paternalistic tool has probing questions to identify ethical issues and lead reviewers to resolve these. Adapting these into one tool allows for the review to be more in-depth and more complete than if only one tool were used. The adapted tools can be seen in Appendix 2.

The Stewardship model was chosen primarily because it was classified as patient-centered in the qualitative content analysis of the literature review in chapter three. Since the theoretical framework of analysis is PCC, it is pertinent that the review tool has patient-centered values and principles exemplified in the tool's review criteria. Further, this tool is congruent with Canada's position as a liberal state in which "it is the state's business to uphold and defend certain fundamental individual rights [and] it is also the state's responsibility to care for the welfare of all citizens" (*An Ethical Framework*, 2014). Further, it aligns well with Canada's position on universal health care, where "each person's welfare, and that of the whole community, matters to everyone" (*An Ethical Framework*, 2014). Thus, this tool is an appropriate standard to hold Canadian healthcare policies to, based on Canada's current social and political position.

Adapting the tool for potentially paternalistic policies is justified by the restrictive nature of gamete reimbursement policy. Prohibitive or behaviour controlling policy actions are not necessarily paternalistic. However, policies that strongly control or influence the actions of a

population may be criticized as paternalistic – rightfully or not. Since Canada has decided to 1) criminally prohibit commercial sale of gametes and 2) control reimbursement of related expenses, these policies could be considered paternalistic actions. Still, it may be presumptuous to accuse the policies of being paternalistic without specifically addressing this concern. Since a tool specifically for this purpose was identified, it is suitable to apply it to the policy. This policy tool, proposed by Bellefleur and Keeling (2018) of the National Collaborating Centre for Health Public Policy, "propose[s] adopting a generally anti-paternalist stance for the ethical analysis of policies or interventions" but also promotes the belief "that further analysis should be conducted to determine if the policy is ethically justifiable; in fact, it may be justifiable for very good reasons."(Bellefleur & Keeling, 2018). Therefore, this tool is applicable to elucidate if the policy at hand is, in fact, paternalistic and whether or not for justifiable reasons.

1. *Concerning goals, public health programmes should aim to reduce the risks of ill health that people might impose on each other*

The aim of the policy for reimbursing gamete donors is to ensure compliance with the prohibition of purchasing gametes. The purpose of prohibiting commercialization of gamete donation is to prevent exploitation, a goal that is primarily concerned with the health and welfare of Canadian gamete donors. Further, it aims to reduce the risks of ill-health imposed by others by reducing the risk of other's exploiting gamete donors. Thus, the policy meets this criterion.

2. *Aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing*

The policy on reimbursing gamete donors does not relate to a physical environment, but to a social environment. It aims to ensure that gamete donors are not taken advantage of by using

financial incentives and aims to ensure that reimbursement does not disguise such incentives. Thus, it aims to insulate the environment within these exchanges. Since unregulated reimbursement practices have led some gamete donors into an unsafe, underground market where donors have been discouraged to report misconduct or non-compliance (Gruben, 2013), the policies proposed to regulate reimbursement ideally aim to "ensure an environment that sustains good health".[14]

3. *Pay special attention to the health of children and other vulnerable people;*

The proposed policy has some specialized attention to children as vulnerable people in this context. The model for reimbursement attempts to prevent children from being commodified as a result of financial value being assigned to the tissues that they result from. Further, it aims to avoid undue coercion on vulnerable people, underscored by the belief that "…money allocates risk to those with fewer opportunities to acquire an equivalent amount through other means" (Ikemoto, 2016, p. 255). The policy itself allows for costs related to caring for dependents to be reimbursed, recognizing the responsibilities towards vulnerable people in donors lives. However, there are gaps in their attention to women donors. Primarily, they do not recognize the difference in needs between oocyte and sperm donors. Donating ova is an undeniably a more complex medical procedure that may, even in the publicly funded Canadian system, be an out-of-pocket expense. This is alluded to by allowing "Expenditures for other items or services that are provided by or recommended in writing by a qualified medical practitioner". While these may allow for expenses that are legitimately related to the donation that are not listed, it does not explicitly address the unique needs of oocyte donors. The only expense that is specific to oocyte donors is "Expenditures for medication". Yet, as previously mentioned, oocyte donors are not

[14] Policy proposals for the safety of sperm and ova would be more relevant for this step, as they are related to physical safety.

eligible to receive work-related reimbursement in the case of lost wages. This is a significant oversight of the medical procedure that ova donation requires. Thus, the policy partly but not fully upholds this criterion.

4. *Aim to ensure that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise*

This step can be used to address how straightforward, pragmatic, and "easy" the policies make reimbursing gamete donors for IPs. Presently, the policies have clear instructions on what is required for reimbursement, such as what receipts and paperwork should be complete and how long it should be kept for. This is helpful for gamete donors to comply with the regulations and partake in a safe donation.

There is still little, if any, information on the "verifiable process" that the proposals refer to. They may be referring to the policy sections 45-58, which control administration and enforcement of the Act. Explaining the verifiable process and mechanism for the reimbursement process within the policy itself would be instrumental to ensuring it is easy for people to follow the policy and therefore donate gametes or accept donated gametes in a safe and healthy way.

5. *Ensure that people have appropriate access to medical services*

This goal is difficult to achieve through this policy since the act does not mandate these procedures are covered by Medicare, private insurance, or are accessible to everyone[15]. It is more applicable to address this step regarding whether the reimbursements allow for appropriate access to medical services or includes reasonable medical services for reimbursement.

[15] Universal coverage for assisted reproductive technologies was recommended by the Baird Report (Baird et al., 1993), yet was not mandated by the federal government and coverage differs between provinces, if there is any at all. While not in the scope of this thesis, the ethical obligation to provide AHR as a medical service has considerably relevant concerns of justice and equality.

The eligible expenditures allow for most to access medical services by allowing travel, care for dependents, prescribed products/services, counselling services, drugs/devices, and obtaining medical records to be reimbursed. However, the exclusion of loss of work-related income limits gamete donors' access to medical services because of the necessary appointments that conflict with work hours. Further, the exclusion of reimbursing expenses that are required for companions to assist oocyte donors limits the accessibility of medical services for oocyte donors specifically. Therefore, there is still a gap in the policy's ability to ensure donors have appropriate access to medical services.

6. *Aim to reduce unfair health inequalities*

By allowing gamete donors some sort of recuperation of expenses due to donating oocytes or sperm, the policy attempts to reduce the unfair burden placed on gamete donors for the benefit of IPs and fertility agencies. In this way, the policy does aim to reduce unfair health inequality, which is the unfair financial burden of the donation process.

However, the policy's treatment of sperm and oocyte donors as the same ignores the larger burden on female donors as opposed to male donors. Donating oocytes requires more time, medical risk, and medical intervention. Yet, HC treats both donors as equivalent, disregarding the clear difference in health consequences of donation. This gap in policy ignores the inequality that oocyte donors experience, since "women are generally at a greater risk than men in the use of reproductive technologies, and, consequently, women are disproportionately vulnerable to their misuse" (Cattapan, 2013). Further, not distinguishing between sperm and oocyte donors ignores the original principles of the AHRA, one which was that "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" ("Assisted Human Reproduction Act," 2004). The treatment of sperm and oocyte donors as having indistinct types and extent of expenses not only does not help reduce health inequalities but systematically reinforces them.

In terms of constraints, such programmes should:

1. *Not attempt to coerce adults to lead healthy lives*

Regulating eligible expenditures for gamete donation imposes parameters on the types of expenses that may be reimbursed. It does not prohibit or explicitly discourage people from donating due to the medically invasive and risk-prone procedure for oocyte donors. The constraint is focused on the financial transaction regarding the intervention, so it does not constrain people's choices regarding donating gametes or not. Thus, the policy meets this requirement and does not unduly influence adults to lead healthy lives or avoid health risks.

2. *Minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate*

Prohibiting payment for gametes and defining the expenses that are reimbursable was initially introduced into criminal law in 2004 by using the Royal Commission for New Reproductive Technologies recommendations. These recommendations were in part based on public engagement at hearings, phone calls, and random surveys of Canadians. The new policy proposals have been in public consultation processes for about 1.5 years and will come to a close in early 2019. The policies, therefore, have received a notable amount of public discourse and democratic processes. The policies do not seek informed consent to limit reimbursable expenses, but they also do not obligate IPs to reimburse expenses at all. In some ways, they give IPs the

choice to reimburse or not, but they do limit the choices of what they may reimburse the donor for.

Still, the consent of donors and IPs to not engage in commercial donation or compensation is enforced without individual consent. As such, the following questions from (Bellefleur & Keeling, 2018) policy review tool to determine if this policy is paternalistic.

Is the policy actually paternalistic/Is the justification for the policy based on one or even several paternalistic reasons or is it based in infantilizing, beneficent, or harm principle reasons?

- *Does the policy actually interfere with the freedom of the individuals it is intended to help or protect?*

The proposed policy interferes with an individual's negative freedom, insofar as it eliminates their freedom to partake in commercial gamete donation. It also restricts their choices by restricting the types of expenditures they are able to be reimbursed for and limits IPs choices in expenditures they can reimburse gamete donors for. The reasoning given for this prohibition is "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" ("Assisted Human Reproduction Act," 2004). Primary justification of the prohibition and limits is the possibility of exploitation that commercialization raises. Whether this interference is unwanted is not well understood in Canada, but due to the prevalent gamete donation tourism, it seems reasonable to say there is disagreement on the appropriateness of a state-enforced prohibition of payment or compensation prohibition (Downie & Baylis, 2013). Considering the policy's level of enforcement and justification, it interferes with the free will of Canadian gamete donors and IPs.

- *If the policy interferes with the freedom of certain persons, were the latter involved in the process of developing the policy or intervention? Given their level of involvement and their opinions, can they be thought of as having consented to this interference?*

While it is unclear whether Canadian stakeholders were involved in the development of the policy, it is clear that they were invited to share input and feedback on the proposed policies more than once. Under the assumption that their feedback was given serious, thoughtful consideration by HC, then the stakeholders had involvement in this policy development.

Harm Principle Considerations

- *With whom or what does the policy interfere? Citizens/consumers or businesses?*

The interference can be seen from different perspectives – it interferes with IPs freedom to pay gamete donors as consumers, it interferes with fertility agencies from paying gamete donors as businesses, and it interferes with gamete donor's freedom to collect payment for gametes. Gamete donors cannot be criminally liable for collecting payment, but IPs are criminally liable for paying donors. IPs could be considered "consumers", as they pay for a "product" to be provided to them. The interference on them would more accurately be described as interference on a "consumer". Therefore, the policy interferes with both consumers (IPs) and businesses (fertility agencies or third-parties).

- *Who does the policy seek to protect? The persons with whom it interferes, other persons or society in general?*

One of the aims of this policy is to protect gamete donors from exploitation and protect the children born from donated gametes from commodification. Thus, this policy aims to protect parties from others, not themselves. First, the law does not make gamete donors criminally liable for accepting payment but makes the party who pays for gametes criminally liable. Therefore,

the protection is aimed at protecting donors from being taken advantage of and protects them against the actions of others (primarily, fertility agencies and IPs).

In addition, since the prohibition was enacted to protect those involved from exploitation, it inherently involves an outside source and an interaction with others. Exploitation is described by Maged El Setouhy (2004) as when a person unduly benefits from interacting with someone else. The concern of this policy is not how a gamete donors actions impact the gamete donor, but how the actions of others will impact the donor. Further, the concern for commodification only materializes if a different person is commodifying the gametes or resulting child. Therefore, the policy aims to protect gamete donors from others exploiting them and protect children who result from donation to not be commodities to others.

- *Who supports such protection and who opposes it?*

While there is widespread agreement that the goals of protecting against exploitation are important, there is a disagreement on how to achieve such protections. Some have raised the concern that "prohibiting payment has made recruitment [of sperm donors] very difficult in Canada" (Del Valle, 2008). Given this particular argument was made by a fertility tissue bank, it seems that fertility banks and services would have reason to not support the ban on compensation. Still, other authors have shown concern over the issues of donor gamete availability in the absence of payment (Reid, Ram, & Brown, 2006; Yee, Hitkari, & Greenblatt, 2007). In addition, the Canadian Fertility and Andrology Society, a non-profit society for fertility specialists and scientists, have recently released a statement in support of decriminalizing compensation for gamete donors. Their reason for this is that "current federal legislation, introduced in 2004, has failed in its stated goals of protecting health, safety and rights and has put Canadians at risk. Prohibiting compensation has created a significant roadblock for

prospective parents who face fertility challenges as they seek to build their families." It seems that those who would benefit from an increase in the number of gametes, such as fertility agencies, tissue banks, and lawyers, may not support these protections.

However, those concerned with patient safety and equality may support the criminal prohibitions as protections against potential exploitation. When there are incentives to donate gamete, they may "…select those who need money as donors, and creat[e] an unequal distribution of burden between the wealthy and the poor" (Reid et al., 2006, p. 41). Baylis (2018) points out that decriminalizing payment serves the interests of lawyers, fertility doctors, and other business people who would benefit from compensatory models, but that it is not obvious how the interests of patients and users of these technologies are served. Further, at the Canadian Institute of Health Research (CIHR) "Best Brains Exchange" on the AHRA, CIHR indicated that participants were concerned that those who promoted the decriminalization of payment for gamete donation were those who stood to financially gain from it (*CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act*, 2018).

It is unclear what position patients in Canada take, while it seems in other countries the majority agree with compensation within certain limits (Lee et al., 2017; Provoost, Van Rompuy, & Pennings, 2018). Further, there is evidence that Canadians are going abroad to participate in commercial donation, indicating their acceptance of this model (Yee et al., 2007). The dearth of knowledge of Canadian patient opinions in this area is troubling since their interests are primarily affected by these prohibitions and regulations.

In summary, it seems that some fertility agencies, lawyers, and scientists disagree with the protections implied by prohibiting commercial gamete donation, while scholars, other lawyers and fertility specialists agree with the protections. While it is unclear what Canadian patients feel

towards compensation, there is evidence to say suggest they may not support the prohibitions against commercialization.

3. *Seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values.*

Regulating the reimbursement of expenses for gametes donors, while interfering with complete freedom, does seek to minimize the pure altruistic system that may be unduly intrusive. Not allowing reimbursement of expenses would not only be intrusive, but it would undermine the burden of donating. It also would cause a significant drop in the availability of donor gametes and thus create problems for IPs who require this resource. Therefore, this reimbursement regulation policy in some ways attempts to minimize an intrusive intervention of complete prohibition by allowing some reimbursable expenditures.

Conclusion

Gamete donation in Canada has been a contentious activity since assisted reproductive technologies began to garner attention in the early 1980s. The Baird report originally positioned the Royal Commission against oocyte donation from anyone who was not already undergoing oocyte extraction (Baird et al., 1993). No prohibition on the practice of gamete donation was introduced in the final Act, but it did consist of a criminal ban on paying for gametes. The use of criminal law in the AHRA has been criticized by multiple scholars as too rigid and the Canadian government's claims of a social consensus among Canadians on the immorality of the practice has been cited not entirely true (Campbell, 2002; *CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act*). Despite the original intentions of HC to introduce regulations for reimbursing gamete donors, at the time of writing the regulations has yet to be put into force. The lack of regulations for the past 14 years has complicated reimbursement for

gamete donation. Some indicate it is still illegal without regulations, while others indicate it is not currently within the scope of Canadian law (Downie & Baylis, 2013; Nelson, 2013; D. Snow et al., 2015). Ambiguous legal status of gamete donor reimbursement resulted in the AHRA being morally incoherent, uncomprehensive, and ineffective.

The proposed regulations present an opportunity to reshape the AHRA into a law that can allow for careful, respectful, and beneficial use of assisted reproductive technologies. To achieve this, it is valuable to consider these proposals from a PCC framework. To fulfill the mandate of the AHRA, gamete donors must be considered patients receiving medical care and, as a result, be treated with no less care than other patients elsewhere. Thus, proposals that impact gamete donors need ethical scrutiny by patient-centered standards.

The patient-centered ethical analysis presented here was introduced by giving a brief overview of the existing AHRA, the proposed regulatory framework, and feedback that was received by HC. Following this, the proposed regulatory actions were assessed using PCC values. It was determined that the HC proposals uphold PCC by permitting reimbursements of expenses, striving for clarity and structure of the regulations, by seeking stakeholder feedback for the proposals during the consultation process, and taking action to prevent exploitation and commodification of human life.

However, there are shortcomings of the proposals and their capacity to uphold PCC. First, the proposals seek to achieve communication by clarifying and structuring the regulations, but the actions proposed are surface level and may not foster the understanding of the regulations in a patient-centered way. Second, restricting reimbursements to a single list of eligible expenses falls short of respecting relational autonomy. Third, the delay of the reimbursement regulations to be developed and enforced undermined values of PCC by leaving gamete donation

reimbursement unregulated. Finally, the proposals lack clear avenues that patients may take to report noncompliance or grievances with the reimbursement regulations to HC. The lack of effective measures to be taken when the regulatory framework is not achieving its goals undermine the values of PCC and, more problematically, the values embraced by the AHRA.

The ethical review using an adaptation of two tools designed specifically for ethically reviewing health policy revealed another serious consideration of this policy. An important one is the absence of a distinction between oocyte and sperm donors. Treating oocyte and sperm donors equally disregard the disproportionate risks, expense, and time that is involved with oocyte donation. The amalgamation of what "reasonable" expenses are for sperm and oocyte donors undermines the extent of the difference in the burden that oocyte donors bear compared to sperm donors, thereby reinforcing existing health inequalities between these groups.

Applying these tools to the proposed policy revealed that the policy is not paternalistic, rather it is based on the harm principle. This conclusion was reached based on the notion that "Paternalistic policies are intended to protect people from themselves, not from the actions of other people" (Bellefleur & Keeling, 2018). Controlling gamete donor reimbursement is not meant to protect gamete donors from themselves, but from being taken advantage of by those who are purchasing gametes. Additionally, it aims to protect resulting children from commodification, which by nature is imposed by others. Therefore, limiting the individual freedoms of gamete donors and IPs aims to protect these patients from the potential harm imposed by the fertility industry. Based on this, the policy was not deemed paternalistic but as based on the harm principle.

Overall, the proposal of gamete donor reimbursement regulations by HC indicates a good evolution in Canadian AHR policy. While this analysis pointed out substantial areas that need

attention, they still presented other proposals that were aligned with PCC values. A summary of these conclusions can be seen in Table 9. Public health policy may require applying ethical norms that differ from those in clinical care, one being the prioritization of prevention in the goals of public health interventions (Dawson, 2011). Section 12 proposals focus on preventing certain activities from occurring that may lead to exploitation by restricting the types of reimbursements and how these are documented. Still, the issue of exploitation concerns individual patients and the policies aimed at preventing it should align with values concerned with patients in addition to public health ethics. Thus, the restrictions should be designed to uphold values of PCC, including respect for relational autonomy, communication, respect for human dignity, and care. In order for these proposals to be fully in line with these values, changes need to be made primarily to the eligibility of reimbursements, development and availability of complaint mechanisms, the distinction between oocyte and sperm donors, and indicating regular audits to the regulatory framework. These actions would take HC's proposals a step forward in putting patients at the centre of gamete donor policy: where they belong.

References

Ariss, R. (1996). The Ethic of Care in the Final Report of the Royal Commission on New Reproductive Technologies. *Queen's Law Journal, 22*, 1-51.

Assisted Human Reproduction Act, C-13 C.F.R. (2004).

Attorney General of Canada v. Attorney General of Quebec Reference *re: assisted human reproduction act,* SCC 61 (2010 SCC 61). Retrieved from https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/7905/index.do

Baird, P., Jantzen, G., McCutcheon, S. E. M., Knoppers, B., & Scorsone, S. (1993). *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies.* Ottawa, Canada: Canada Communications Group.

Baylis, F. (2018). Canada's Prohibition on Payment for Surrogacy, Eggs, and Sperm. *J Obstet Gynaecol Can, 40*(12), 1. doi:10.1016/j.jogc.2018.08.005

BC Ministry of Health. (2015). The British Columbia Patient-Centered Care Framework. British Columbia. Retrieved From: http://www.health.gov.bc.ca/library/publications/year/2014/Setting-priorities-BC-Health-Feb14.pdf

Bellefleur, O., & Keeling, M. (2018). *How can we (and why should we) analyze the ethics of paternalistic policies in public health?* Retrieved from Montreal, Quebec: National Collaborating Centre for Healthy Public Policy

Bracewell-Milnes, T., Saso, S., Bora, S., Ismail, A. M., Al-Memar, M., Hamed, A. H., . . . Thum, M. Y. (2016). Investigating psychosocial attitudes, motivations and experiences of oocyte donors, recipients and egg sharers: a systematic review. *Hum Reprod Update, 22*(4), 450-465. doi:10.1093/humupd/dmw006

Cameron, A., & Gruben, V. (2011). Quebec's Constitutional Challenges to the Assisted Human Reproduction Act: Overlooking Women's Reproductive Autonomy? In S. Patterson, F. Scala, & M. Sokolon (Eds.), *Fertile Ground: Exploring Reproduction in Canada*. (pp. 125-151). Montreal, Quebec, Canada: McGill-Queen's University Press.

Campbell, A. (2002). A Place for Criminal Law in the Regulation of Reproductive Technologies. *Health Law Journal, 10*, 77-101.

Canadian Medical Association. (2018). *Canadian Medical Association Strategic Plan: CMA 2020*. Retrieved from https://www.cma.ca/sites/default/files/pdf/Member-Proposals/cma2020-strategic-plan-e.pdf

Carse, A. (1998). Impartial Principle and Moral Context: Securing a Place for the Particular in Ethical Theory. *Journal of Medicine and Philosophy, 23*(2), 152-169.

Cattapan, A. (2013). Rhetoric and Reality: "Protecting" Women in Canadian Public Policy on Assisted Human Reproduction. *Canadian Journal of Women and the Law, 25*(2), 202-220. doi:10.3138/cjwl.25.2.202

CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act. (2018). Ottawa, Ontario, Canada.

Dawson, A. (2011). Resetting the Parameters. In A. Dawson (Ed.), *Public health ethics: Key concepts and issues in policy and Practice (Cambridge medicine)*. (pp. 1-19) Cambridge, England: Cambridge University Press.

Del Valle, A. (2008). Anonymous semen donor recruitment without reimbrusement in Canada. *Ethics, Bioscience, and Life, 3*(2), 15-20.

Downie, J., & Baylis, F. (2013). Transnational Trade in Human Eggs: Law, Policy, and (In)action in Canada. *Journal of Law, Medicine, and Ethics, 41*(Spring 2013), 224-239.

Düwell, M. (2017). Why Bioethics isn't Ready for Human Dignity. In R. Debes (Ed.), *Dignity: A History* (pp. 323-332). Oxford, England: Oxford Scholarship Online.

Edwards, S. (2011). Is there a distinctive care ethics? *Nursing Ethics, 18*(2), 184-191.

Ells, C., Hunt, M., & Chambers-Evans, J. (2011). Relational Autonomy as an essential component to patient-centered care. *International Journal of Feminist Approaches to Bioethics, 4*(2), 79-101.

Epstein, R. M., Fiscella, K., Lesser, C. S., & Stange, K. C. (2010). Why the nation needs a policy push on patient-centered health care. *Health Aff (Millwood), 29*(8), 1489-1495. doi:10.1377/hlthaff.2009.0888

Gilligan, C. (1982). *In a Different Voice: Psychological Theory and Women's Development*. Cambrudge, Massachusetts, USA: Harvard University Press.

Gilligan, C., Ward, J., & Taylor, J. (1988). *Mapping the Moral Domain: A Contribution of Women's Thinking to Psychological Theory and Education* Cambridge, Massachusetts: Harvard University Press.

Gruben, V. (2013). Women as Patients, Not Spare Parts: Examining the Relationship between the Physician and Women Egg Providers. *Canadian Journal of Women and the Law, 25*, 249-283.

Hammell, K. (2013). Client-centred occupational therapy in Canada: Refocusing on core values. *Canadian Journal of Occupational Therapy, 80*(3), 141-149.

Health Canada. (2017). *Towards a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals*. Ottawa, Ontario, Canada: Minister of Health

Health Canada. (2018). *What We Heard: A Summary of Feedback from the Consultation: Toward a Strengthened Human Reproduction Act.* Ottawa, Ontario, Canada: Minister of Health

Ikemoto, L. (2016). Assisted Reproductive Technology Use among Neighbours: Commercialization Concerns in Canada and the United States, in the Global Context. In T. M. Lemmens, Cheryl; Lee, Ian B.; Lemmens, Trudo; Martin, Andrew Flavelle; Milne, Cheryl; Lee, Ian B. (Ed.), *Regulating creation: the law, ethics, and policy of assisted human reproduction* (pp. 253-273). Toronto, Ontario, Canada: University of Toronto Press.

Jordan, C., Belar, C., & Williams, R. S. (2009). Anonymous oocyte donation: a follow-up analysis of donors' experiences. *Journal of Psychosomatic Obstetrics & Gynecology, 25*(2), 145-151. doi:10.1080/1674820400002261

Kalfoglou, A. L., & Gittelsohn, J. (2000). A qualitative follow-up study of women's experiences with oocyte donation. *Hum Reprod, 15*(4), 798-805.

Kant, I., & Abbott, T. K. (1873). *Theory of ethics.* London: Longmans.

Lee, M. S., Farland, L. V., Missmer, S. A., & Ginsburg, E. S. (2017). Limitations on the compensation of gamete donors: a public opinion survey. *Fertil Steril, 107*(6), 1355-1363 e1354. doi:10.1016/j.fertnstert.2017.03.001

Macklin, R. (2003). Dignity is a useless concept. *BMJ Open, 327*, 1419-1420.

Maged El Setouhy, T. A., Francis Anto, Christine Alexandra Clerk, Kwadwo A. Koram, Michael English, Rashid Juma, Catherine Molyneux, Norbert Peshu, Newton Kumwenda, Joseph Mfutso-Bengu, Malcolm Molyneux, Terrie Taylor, Doumbia Aissata Diarra, Saïbou Maiga, Mamadou Sylla, Dione Youssouf, Catherine Olufunke Falade, Segun Gbadegesin, Reidar Lie, Ferdinand Mugusi, David Ngassapa, Julius Ecuru, Ambrose Talisuna, Ezekiel Emanuel. (2004). Moral Standards for Research in Developing Countries from "Reasonable Availability" to "Fair Benefits". *The Hastings Center Report, 34*(3), 17-27.

Morrissey, C. (2016). The value of dignity in and for bioethics: rethinking the terms of the debate. *Theor Med Bioeth, 37*(3), 173-192. doi:10.1007/s11017-016-9368-6

Motluk, A. (2010-04-12). The Human Egg Trade: How Canada's fertility laws are failing donors,doctors, and parents. *The Walrus*. Retrieved from https://thewalrus.ca/the-human-egg-trade/

Nelson, E. (2013). Global Trade and Assisted Reproductive Technologies: Regulatory Challenges in International Surrogacy. *Journal of Law, Medicine, and Ethics*, 240-254.

Nuffield Council on Bioethics. (2014). *An Ethical Framework.* London, England: Nuffield Council on Bioethics. Retrieved from.http://nuffieldbioethics.org/wp-content/uploads/2014/07/Public-health-ethical-issues.pdf

Provoost, V., Van Rompuy, F., & Pennings, G. (2018). Non-donors' attitudes towards sperm donation and their willingness to donate. *J Assist Reprod Genet, 35*(1), 107-118. doi:10.1007/s10815-017-1036-x

Reid, L., Ram, N., & Brown, R. B. (2006). Compensation for Gamete Donation: The Analogy with Jury Duty. *Cambridge Quarterly of Healthcare Ethics, 16*(1), 35-43. doi:10.1017/s0963180107070041

Santana, M. J., Manalili, K., Jolley, R. J., Zelinsky, S., Quan, H., & Lu, M. (2018). How to practice person-centred care: A conceptual framework. *Health Expect, 21*(2), 429-440. doi:10.1111/hex.12640

Skoog Svanberg, A., Lampic, C., Gejerwall, A. L., Gudmundsson, J., Karlstrom, P. O., Solensten, N. G., & Sydsjo, G. (2013). Gamete donors' satisfaction; gender differences and similarities among oocyte and sperm donors in a national sample. *Acta Obstet Gynecol Scand, 92*(9), 1049-1056. doi:10.1111/aogs.12156

Snow, D., Baylis, F., & Downie, J. (2015). Why the Government of Canada Won't Regulate Assisted Human Reproduction: A Modern Mystery. *McGill Journal of Law and Health, 9*(1), 1-16.

Tronto, J. (2013). *Caring Democracy*. New York: NYU Press.

World Health Organization. (2007). People-Centred Health Care: A Policy Framework. Switzerland: World Health Organization. Retrieved from https://iris.wpro.who.int/handle/10665.1/5420

Yee, S. (2009). 'Gift without a price tag': altruism in anonymous semen donation. *Hum Reprod, 24*(1), 3-13. doi:10.1093/humrep/den347

Yee, S., Hitkari, J. A., & Greenblatt, E. M. (2007). A follow-up study of women who donated oocytes to known recipient couples for altruistic reasons. *Hum Reprod, 22*(7), 2040-2050. doi:10.1093/humrep/dem103

Chapter 5 Discussion and Conclusion: Overall Implications of Health Canada's Proposed Policies for Gamete Donor Reimbursement

Introduction

The advancement of reproductive technologies should include addressing the ethical challenges of its accompanying policy. The ethical concerns that surround a reimbursement model for gamete donors are vast and complex. They include respect for autonomous decision-making of patients, commercialization of reproduction and the potential for exploitation. The ultimate goal of this thesis was to formally address these pertinent ethical concerns from a patient-centered perspective in recognition of the specific patient stakes in this policy. With the purpose of achieving this goal, the work here also aimed to seek clarity on the available tools that can be used for health policy ethics review. This thesis presents a comprehensive and informed analysis and review of the policies proposed to regulate reimbursement of gamete donors in Canada.

Relevance to primary care

Primary healthcare "encompasses the practice of all health professionals involved in front-line healthcare delivery" (Bartlett-Esquilant & Rodriguez, 2017, p. 10). Primary healthcare research spans diverse multidisciplinary boundaries and includes, among other things, the policies that govern care (Bartlett-Esquilant & Rodriguez, 2017). Health is influenced by various factors that include health policy and services and as a result, health can be improved via policy action (Seavey et al., 2014). Applicable and relevant research pertaining to health policies is vital for the continued progression of primary healthcare in Canada and globally.

The research undertaken here has several implications for the field of primary care. First, the identification and classification of ethical review tools for health policy may provide valuable tools for applying in the primary care policy setting. Although these tools are not explicitly

indicated for primary care applications, they may be useful for the primary care policy context and undergo further research to validate them in the context of primary care. Applying these tools in the primary care setting has the potential to benefit primary healthcare providers and policymakers to consider the ethical dimensions of their work more carefully and consciously. Further, the review tools can make ethical concepts more applicable for the primary healthcare providers who are not trained in ethics or philosophy. By reducing the complexity of the tool's bioethical theory to qualitative categories, the ethical analysis is made more accessible for the primary healthcare setting, by raising ethical awareness without overbearing healthcare providers. Thus, the review completed in this thesis may be used to improve the ethical considerations in primary healthcare.

Second, primary healthcare is a broad practice that encompasses several health issues. One of these is reproductive health and family planning. The AHRA controls how AHR can be carried out by sperm and egg banks, agencies, and physicians. Despite the existence and prevalence of specialized fertility clinics and specialists, primary healthcare physicians have a responsibility to provide comprehensive care to their patients, including the procedures and functions of fertility medicine to their patients who are or considering being IPs or gamete donors. Though primary healthcare physicians may not specialize in assisted reproductive technologies, it is still valuable for a strong patient-physician relationship that Canadian primary healthcare physicians have the resources to share knowledge AHR policies. This knowledge could help their patients engage in these practices safely and legally.

Third, gamete donors, especially ova donors, are patients who receive medical care, rendering issues surrounding donation deserving of attention from their primary healthcare physicians. Gruben (2013) indicates that the person who performs most of the medical care on an

ova donor, including the stimulation, extraction, and follow-up is her physician. Specifically, Smith (2009) indicates that primary care has a role in several steps of infertility treatment, such as pre-treatment counselling, ovulation drug management and monitoring, and ongoing care, many of which coincide with oocyte donation specifically. These responsibilities obligate the physician to provide ova donors with information on the procedures of egg donation. Oocyte donors are receiving medical attention and "are owed the same duties present in the ordinary physician–patient relationship" (Daar et al., 2016, p. 18). Further, primary care physicians aim to be the first line of care for patients (Bartlett-Esquilant & Rodriguez, 2017; Wong & Haggerty, 2013). This implies that if gamete donors experience something (good or bad) throughout the process of their donation, or is seeking to donate, the first person they seek is likely their primary care physician. Therefore, it is likely that primary care providers are involved in the process at some level, whether that means initial tests for eligibility, initiating the cycle(s) of ovulation induction, or simply discussing it and its aftermath with the patient (Smith, 2009; Wilkes & Murdoch, 2012). As a result, the governance of gamete donation should be of interest and importance to primary care physicians. The implementation of Canadian gamete donor reimbursement regulations is pertinent for primary care physicians to promote the wellbeing, safety, and health of their patients who may be current or future gamete donors.

Sperm and Egg Donors: The Same?

A significant problem that was seen in the proposed regulations in the context of patient-centered care (PCC) for reimbursing gamete donors is the ignorance of the gendered nature of gamete donation. Treating oocyte and sperm donors the same in terms of their allowable expenses is a concerning oversight, considering the differences in the donation process. Reproductive technologies generally "take place primarily on the bodies of women, and as such

represent a critical site for the contestation of women's reproductive autonomy and equality" (Cameron & Gruben, 2011, p. 6). Specifically, oocyte donors experience "…more discomfort, risk, and physical intrusion than sperm donation" (Daar et al., 2016, p. 18). The fact that there is a sparse acknowledgement of the distinct impact of reimbursing oocyte donors compared to sperm donors is one of the more serious oversights of this regulatory framework.

Further, the AHRA principles explicitly recognize the increased burden women and children bear from using AHR, making the exclusion of the distinction in the proposed regulations for reimbursement inconsistent with the AHRA itself. The AHRA states that "2(c) 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;" ("Assisted Human Reproduction Act," 2004). Therefore, while the AHRA should align with this principle, the proposed regulations for section 12 of the Act fail to uphold this.

Health policies, according to the Stewardship model, should aim to reduce health inequalities (An Ethical Framework, 2014). Regulating oocyte and sperm donors' reimbursements as the same does not embody equality, but rather maintain conditions of health inequality between male and female donors. Equality cannot be achieved by simply treating patients the same. Rather, they should ensure that people have the resources they need within their particular circumstances. Policies regulating the reimbursement of gamete donors should aim to alleviate the disproportionate burdens of oocyte donation by acknowledging the need to allow for a wider range of eligible reimbursements than sperm donors. Considering that oocyte donors are subject to much higher medical risks and commit substantially more time to donate, justice entitles them to receive differential attention in these policies corresponding to the greater

burdens they are exposed to. Even when considering the time that sperm donors spend in interviews and pre-donation appointments, “sperm donor reimbursement rates are reasonably considered to underestimate the amount that is appropriate for women providing oocytes” (Daar et al., 2016, p. 18). Additionally, “egg production is significantly more invasive-it requires weeks of shots, tests, and a painful surgical procedure. In contrast, sperm production is a relatively quick and painless process.” (Gruben, 2013, p. 252). Oocyte donors contribute more resources, such as time, energy, risk, and medical costs to gamete donation than sperm donors. As a result, inequality of expended resources arises between oocyte and sperm donors. If their contributions are not equal, then it is not defensible to treat them equally in a policy that regulates how they are reimbursed.

The Future of the AHRA: Legal and Regulatory Models

Though not in the scope of Health Canada’s (HC) current regulatory project, the future of the AHRA as it stands is being questioned. HC indicated they may look into future amendments to the Act to keep pace with advancements in assisted human reproduction and with changing attitudes of society towards these technologies (*Health Canada*, 2017). Further, Mr. Anthony Housefather, a Canadian MP, has put forth an independent bill to amend the AHRA ("An Act to amend the Assisted Human Reproduction Act," 2018). In addition, given that the AHRA has been poorly enforced to-date, its current effectiveness is questionable (Cattapan, 2013). Whether the Canadian federal government will continue to criminally control activities of reproduction or not is unclear, but their actions will impact Canadian gamete donation immensely.

Regarding gamete donation regulations specifically, Mr. Housefather’s bill would decriminalize payment for donation and redirect the onus of reimbursement and commercial donation policies to provinces, by replacing section 7(1) from “No person shall purchase, offer to

purchase or advertise for the purchase of sperm or ova from a donor or a person acting on behalf of a donor" to "no person shall counsel or induce a person to donate their sperm or ova, or perform any medical procedure to assist a person to donate their sperm or ova, knowing or having reason to believe that the person is under 18 years of age, is incapable of consenting to the donation or is being coerced by a third party to donate" ("An Act to amend the Assisted Human Reproduction Act," 2018). Adding to the discourse on commercial gamete donation, in a Canadian Institute of Health Research "Best Brains Exchange" session discussing the AHRA (*CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act* 2018), where experts on a particular topic of interest are invited to present and contribute to academic engagement with one another, some participants expressed that criminal law is an inappropriate tool for addressing commodification concerns. These movements have prompted several valuable questions: Have Canadian values shifted towards accepting, and even promoting, a compensation model for gamete donation? Is the movement toward a compensation model fueled by the interests of other stakeholders such as lawyers and fertility agencies that would benefit from such arrangements?

On one hand, a factor that has hindered the usefulness and progressive dialogue of the Act is its criminal nature, both ultimately contributing to a lag in effective AHR policy. The criminal assignment of any payment made to donors not specifically as a "reimbursement" has suppressed meaningful conversations on its justification. Even if the prohibition is ethically reasonable, it has limited public discourse and advancement that are consistent with the values of Canadian society. This negative impact is interpreted by the lack of research on Canadian gamete donors' attitudes towards payment or experiences with payment of gamete donors since it is a challenge to gain these perspectives on criminal activities (Gruben, 2013). A supporter of a regulatory

approach is Professor Knoppers[16], who expressed that "the AHR Act has stifled debates by virtue of its prohibition and associated criminal penalties" (*CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act,* 2018, p. 6).

In contrast to those who advocate for less federal oversight, some stakeholders agree with the use of federal law for AHR and, despite its shortcomings, want to continue working with the AHRA. One of the proponents for the AHRA is Dr. Francois Baylis[17]. She has voiced compelling concerns with distributing regulation of commercialization, due to the inherent conflict of interest (*CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act,* 2018). She argues against eliminating the AHRA by pointing out that "provincial patchwork would benefit clinicians, lawyers, and brokers who want to increase their respective businesses and who currently advocate for the commercialization of reproduction" (Baylis, 2018, p. 1). These concerns for the improper distribution of benefits to powerful people is a social and moral issue that is arguably more effectively dealt with at a federal level (Baird et al., 1993). There were additional participants at the Best Brains Exchange who showed support for a criminal law approach to gamete donation practices (*CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act,* 2018). Campbell (2002) also argued for federal approaches preceding the assent of the AHRA to ensure democratic accountability to the public. Protecting Canadians health and safety are at the root of advocating a federal regulatory approach, along with concern of losing these protections by using a less concrete and centralized regulatory tool.

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[17] Dr. Francois Baylis is a professor at Dalhousie University in the department of Obstetrics and Gynaecology and a Canada Research Chair in Bioethics.

However, legal approaches may not be the appropriate tool for reproductive medicine, considering it is ingrained social and political gender inequality. A feminist-oriented perspective on the AHRA could find a government policy for oocyte donor reimbursement as another attempt for male-dominated institutional control over women's bodies. As S. Sherwin (1989) points out, feminist theory is not solely concerned with individual and relational contexts, but with political and social contexts. The political control of women's bodies within the AHRA is a reason for concern over its ethical permissibility in general, especially considering the criminal nature of the policy. The government's introduction of medical and social norms surrounding the reproductive functions of women may reinforce attitudes that women's bodies are not their own but are to be systematically controlled by male-dominated social structures.

The purpose of this thesis was not to determine which regulatory approach is more appropriate for AHR or to discuss the usefulness of the AHRA in general. Yet, an invaluable factor moving forward is the attention to patient experiences and concerns. There needs to be a focus on aligning the AHRA principles with prioritizing patient interests, not using this language to justify controlling behaviour without ensuring it prevents harm to patients. The principles recognized by Parliament in the AHRA to "…tak[e] appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies…" and "…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…" are commitments of the federal government to patient interests. Thus, going forward they need to ensure their AHR policies effectively deliver on these commitments.

If compensation to gamete donors is permitted, it should be in the interests of patients (IPs and donors), not in the sole interest of lawyers, physicians, or fertility agencies. If compensation

only benefits lawyers, physicians, or fertility agencies, then it would be exploitative and unjust to patients. Finally, the AHRA and its regulatory framework need to be put into practice, rather than remaining unenforced and resulting in illicit activities that promote more exploitation.

A PCC framework offers a breadth of ethical insights on the proposed Canadian gamete donor reimbursement policies. Communication regarding gamete commercialization within Canada needs to improve, regardless of its future in criminal law. HC needs to promote positive engagement with stakeholders that alleviates fear or judgement based on the legal status of commercialization. Moreover, patient interests should be a core consideration for gamete donor policy. The relational autonomous claims of patients should not be ignored in the name of public health actions without sound justification and every effort should be made to ensure patient freedom is minimally interfered with. Finally, proper enforcement and continuous monitoring of implemented policies are needed to ensure gamete donors and IPs are sufficiently cared for within their respective donor agreements.

Conclusion

The work here applied a PCC ethical framework to a critical ethical analysis and review of Canada's policy proposals for reimbursing gamete donors. The thesis objective, which was to use a PCC theoretical framework to analyze HC's proposed regulatory framework for reimbursing gamete donors, was achieved by gaining an understanding of the theoretical concepts of PCC, searching and classifying tools designed for health policy ethics review, and applying these to HC's policy proposals for gamete donor reimbursement.

In Chapter 2, an introductory literature review on ethics of care and PCC theories was done. Ethics of care was found to be a theory that attributes importance to the value of care and fundamentally redefines the nature of humanity as inherently dependent, shifting from traditional

ways that morality and human agency is conceptualized. The PCC literature defined features of the practice and theory, which included seeing patients as whole persons, sharing power and decision making, and supporting patients in the context of their lived experiences. The review also revealed four important values of PCC: communication, respect for autonomy, respect for dignity, and care as a value. This review of the literature laid the theoretical groundwork for the following analysis.

Chapter 3 presented a systematic search and review that compiled and analyzed tools that were designed for health policy ethics review. In this review, 13 tools were identified and qualitatively analyzed. Two of these tools were chosen to be adapted to the objective of this thesis.

In Chapter 4, the proposed gamete donor reimbursement policy and the feedback received on this proposal was outlined using reports that were available from HC. The policy proposal was critically analyzed using the PCC values that were identified in Chapter 2. This critical analysis found that the development and proposal of this policy demonstrated care by attempting to prevent exploitation of gamete donors and valued communication by seeking stakeholder feedback and requiring a declaration to be signed by donors and IPs. However, it did not consistently respect the autonomy of patients in narrowing the eligible expenses and did not rectify the negative impacts on patients caused by HC's latency in developing these policies.

A review of the policy was presented in Chapter 4 using two tools from the systematic search and review, which were the Stewardship Approach (*An Ethical Framework,* 2014) and Analyzing Paternalistic Policies (Bellefleur and Keeling, 2018). These tools revealed that the proposed policy was not paternalistic but based on the harm principle. They also showed that the proposed policy did not fully uphold equality between oocyte and sperm donors by not

adequately differentiation their eligible expenses. However, the proposed policy met the Stewardship Approaches criteria that it aims to ensure the welfare of gamete donors.

The overarching products of this thesis were the identification and application of sequential ethical review tools for health policy and a critical analysis of Canadian health policy proposal for reimbursing gamete donors. By achieving the goal of this thesis, this work provides ethical input on the new policy for reimbursing gamete donors in Canada.

Future Directions

As Western medicine continues to shift towards evidence-based practice and policy, ethical review and analysis of policy has become more necessary. The use of supporting evidence in policy-making should be balanced with ethical justification. Evidence-based practices in health are both effective and morally valuable. However, basing policy on evidence alone may risk the moral features of policy to be ignored and obligations unmet. Criticisms of evidence-based policy are that it ignores public values and key democratic deliberation on values (Ansell & Geyer, 2017).

The primary objective of this research was to use a PCC theoretical framework to analyze HC's proposed regulatory framework for reimbursing gamete donors and to assess its ethical implications. A care centred theory of ethics, such as PCC, can contribute to positively reshaping health policy (Tronto, 2013). Noddings argues that rigid policy is often defended by impartiality, yet such impartiality does not truly exist in practice (Noddings, 2002). Thus,

> "…so long as impartiality is held as the ideal, we will continue to tinker with rules and penalties in the hope that reality can be made congruent with the theoretical ideal. Even at the theoretical level there is something obviously wrong

with most applications of impartiality. Events that are similar on the surface involve very different selves and, thus, are really different events." (p. 232).

Care approaches, like PCC, do not support hypothetical "impartial" policy because it can only be applied to impartial situations. Rather, they acknowledge that situations that appear equal are often layered with complex differences. This particularity allows health policy to be developed and analyzed as it is, not as it is perceived or desired to be.

Healthcare in Canada is headed towards patient-centered practices and attitudes. Provinces like Ontario and British Columbia have incorporated PCC initiatives into health services, such as Ontario's family health team model (Rosser et al., 2011) and the patient-centered framework for British Columbia's ministry of health (BC Ministry of Health, 2015). Canada has recently followed suit and the Canadian Medical Association has proposed a strategic plan to empower patient voices in healthcare (Canadian Medical Association, 2018). The reality of the complex relationship between clinical healthcare and healthcare policy is that they are in a feedback loop. Changes to one inevitably influence changes in the other, cyclically and continuously. As a result, even if the "nature of public health" is different from clinical medicine (Dawson, 2011), they cannot be separated or treated independently from each other. Actions justified in one should be justified in the other; if PCC is vital to clinical medicine, then it should be reflected in policies surrounding clinical practice. The application of a PCC ethical framework to healthcare policy could help with a successful transition to and maintenance of PCC practice in the ongoing effort to the improvement of Canadian healthcare.

References

Abbasi, M., Majdzadeh, R., Zali, A., Karimi, A., & Akrami, F. (2018). The evolution of public health ethics frameworks: systematic review of moral values and norms in public health policy. *Med Health Care Philos, 21*(3), 387-402. doi:10.1007/s11019-017-9813-y

An Act to amend the Assisted Human Reproduction Act, C-404 (2018).

Ansell, C., & Geyer, R. (2017). 'Pragmatic complexity' a new foundation for moving beyond 'evidence-based policy making'? *Policy Studies, 38*(2), 149-167. doi:10.1080/01442872.2016.1219033
Ariss, R. (1996). The Ethic of Care in the Final Report of the Royal Commission on New Reproductive Technologies. *Queen's Law Journal, 22*, 1-51.
Assisted Human Reproduction Act, C-13 C.F.R. (2004).
Atkinson, M. M., & Chandler, M. (1983). Strategies for Policy Analysis. In M. M. Atkinson & M. Chandler (Eds.), *The Politics of Canadian Public Policy* (pp. 4-19). Toronto, Ontario, Canada: University of Toronto Press.
Attorney General of Canada v. Attorney General of Quebec Reference *re: assisted human reproduction act,* SCC 61 (2010 SCC 61). Retrieved from https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/7905/index.do
Audet, A. M., Davis, K., & Schoenbaum, S. C. (2006). Adoption of Patient-Centered Care Practices by Physicians. *Arch Intern Med, 166*, 754-759.
Baird, P. (1996). Recommendations of the Canadian Royal Commission on New Reproductive Technologies. *Women's Health Issues, 6*(3), 126-132.
Baird, P., Jantzen, G., McCutcheon, S. E. M., Knoppers, B., & Scorsone, S. (1993). *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies.* Ottawa, Ontario, Canada: Canada Communications Group.
Barry, M., & Edgman-Levitan, S. (2012). Shared Decision Making - the Pinnacle of Patient-Centered Care. *New England Journal of Medicine, 366*(9), 780-781.
Bartlett-Esquilant, G., & Rodriguez, C. (2017). Primary Care Research: The Realm of Paradigmatic Plurality. *McGill Journal of Medicine, 15*, 10-12.
Baum, N., Gollust, S., Goold, S., & Jacobson, P. (2007). Looking Ahead: Addressing ethical challenges in public health. *Global Health Law, Ethics, and Policy, Symposium,* 657-667.
Baylis, F. (2018). Canada's Prohibition on Payment for Surrogacy, Eggs, and Sperm. *J Obstet Gynaecol Can, 40*(12), 1. doi:10.1016/j.jogc.2018.08.005
Baylis, F., & Downie, J. (2013). The Tale of Assisted Reproduction Canada: A Tradegy in Five Acts. *Canadian Journal of Women and the Law, 25*, 183-201. doi:10.3138/ejwl.25.2.183
BC Ministry of Health. (2015). The British Columbia Patient-Centered Care Framework. British Columbia. Retrieved From: http://www.health.gov.bc.ca/library/publications/year/2014/Setting-priorities-BC-Health-Feb14.pdf
Beach, W. A., Easter, D. W., Good, J. S., & Pigeron, E. (2005). Disclosing and responding to cancer "fears" during oncology interviews. *Soc Sci Med, 60*(4), 893-910. doi:10.1016/j.socscimed.2004.06.031
Blyth, E., & Farrand, A. (2005). Reproductive Tourism: A Price Worth Paying for Reproductive Autonomy? *Critical Social Policy,* 25(1), 91-114.
Bushnik, T., Cook, J., Hughes, E., & Tough, S. (2012). Seeking medical help to conceive. *Component of Statistics Canada Catalogue*.
Cameron, A., & Gruben, V. (2011). Quebec's Constitutional Challenges to the Assisted Human Reproduction Act: Overlooking Women's Reproductive Autonomy? In S. Patterson, F. Scala, & M. Sokolon (Eds.), *Fertile Ground: Exploring Reproduction in Canada* (pp. 125-151). Montreal, QC: McGill-Queen's University Press.
Campbell, A. (2002). A Place for Criminal Law in the Regulation of Reproductive Technologies. *Health Law Journal, 10*, 77-101.

Canada Health Act, C-6 C.F.R. (1985).
Canadian Medical Association. (2018). *Canadian Medical Association Strategic Plan: CMA 2020*. Retrieved from https://www.cma.ca/sites/default/files/pdf/Member-Proposals/cma2020-strategic-plan-e.pdf
Carse, A. (1998). Impartial Principle and Moral Context: Securing a Place for the Particular in Ethical Theory. *Journal of Medicine and Philosophy, 23*(2), 152-169.
Cattapan, A. (2013). Rhetoric and Reality: "Protecting" Women in Canadian Public Policy on Assisted Human Reproduction. *Canadian Journal of Women and the Law, 25*(2), 202-220. doi:10.3138/cjwl.25.2.202
Cattapan, A., & Cohen, S. R. (2013). The Devil We Know: The Implications of Bill C-38 for Assisted Human Reproduction in Canada. *Journal of Obstetrics and Gynaecology Canada, 35*(7), 654-656. doi:10.1016/s1701-2163(15)30890-2
Childress, J., Faden, R., Gaare, R., Gostin, L., Kahn, J., Bonnie, R. J., . . . Nieburg, P. (2002). Public health ethics: Mapping the Terrain. *Journal of Law, Medicine, and Ethics, 30*(2), 170-178.
Childress, J. F., & Bernheim, R. G. (2015). Chapter 1 Introduction: A Framework for Public Health Ethics. In R. Bernheim, Childress, J., Bonnie, R., & Melnick, A. (Ed.), *Essentials of public health ethics* (pp. 3-19). Burlington, Massachusetts: Jones & Bartlett Learning.
CIHR Best Brains Exchange: A Path Forward for the Assisted Human Reproduction Act. (2018). Ottawa, ON
Clarke, S. (2016). *Grounding care practices in theory exploring the potential for the ethics of care to provide theoretical justification for patientcentered care.* (Master of Arts Thesis), McGill University, Montreal, Canada.
Clayton, M. F., Latimer, S., Dunn, T. W., & Haas, L. (2011). Assessing patient-centered communication in a family practice setting: how do we measure it, and whose opinion matters? *Patient Educ Couns, 84*(3), 294-302. doi:10.1016/j.pec.2011.05.027
Constand, M., MacDermid, J., Bello-Haas, V., & Law, M. (2014). Scoping review of patient-centered care approaches in healthcare. *BMC Health Services Research, 14*(271), 1-9.
Canadian Constitution Act, 1867. Retrieved From: https://laws-lois.justice.gc.ca/eng/const/
An Act respecting clinical and research activities as regards assisted human reproduction and amending other legistlative provisions, (2004). Retrieved From: https://laws-lois.justice.gc.ca/eng/acts/A-13.4/
Daar, J., Benward, J., Collins, L., Davis, J., Francis, L., Gates, E., . . . Westphal, L. (2016). Financial compensation of oocyte donors: an Ethics Committee opinion. *Fertil Steril, 106*(7), e15-e19. doi:10.1016/j.fertnstert.2016.09.040
Davis, K., Schoenbaum, S. C., & Audet, A. M. (2005). A 2020 vision of patient-centered primary care. *J Gen Intern Med, 20*(10), 953-957. doi:10.1111/j.1525-1497.2005.0178.x
Dawson, A. (2011). Resetting the Parameters. In *Public health ethics : Key concepts and issues in policy and Practice (Cambridge medicine).* A. Dawson (Ed.). Cambridge: Cambridge University Press. (2011).
de Boer, D., Delnoij, D., & Rademakers, J. (2013). The importance of patient-centered care for various patient groups. *Patient Educ Couns, 90*(3), 405-410. doi:10.1016/j.pec.2011.10.002
Downie, J., & Baylis, F. (2013). Transnational Trade in Human Eggs: Law, Policy, and (In)action in Canada. *Journal of Law, Medicine, and Ethics, 41*(Spring 2013), 224-239.

Duggan, P. S., Geller, G., Cooper, L. A., & Beach, M. C. (2006). The moral nature of patient-centeredness: is it "just the right thing to do"? *Patient Educ Couns, 62*(2), 271-276. doi:10.1016/j.pec.2005.08.001
Edwards, S. (2011). Is there a distinctive care ethics? *Nursing Ethics, 18*(2), 8.
Ells, C., Hunt, M., & Chambers-Evans, J. (2011). Relational Autonomy as an essential component to patient-centered care. *International Journal of Feminist Approaches to Bioethics, 4*(2), 79-101.
Entwistle, V. A., & Watt, I. S. (2013). Treating patients as persons: a capabilities approach to support delivery of person-centered care. *Am J Bioeth, 13*(8), 29-39. doi:10.1080/15265161.2013.802060
Epstein, R. M., Fiscella, K., Lesser, C. S., & Stange, K. C. (2010). Why the nation needs a policy push on patient-centered health care. *Health Aff (Millwood), 29*(8), 1489-1495. doi:10.1377/hlthaff.2009.0888
Epstein, R. M., Franks, P., Fiscella, K., Shields, C. G., Meldrum, S. C., Kravitz, R. L., & Duberstein, P. R. (2005). Measuring patient-centered communication in patient-physician consultations: theoretical and practical issues. *Soc Sci Med, 61*(7), 1516-1528. doi:10.1016/j.socscimed.2005.02.001
Epstein, R. M., & Street, R. L., Jr. (2011). The values and value of patient-centered care. *Ann Fam Med, 9*(2), 100-103. doi:10.1370/afm.1239
Farrell, M. H., Kuruvilla, P., Eskra, K. L., Christopher, S. A., & Brienza, R. S. (2009). A method to quantify and compare clinicians' assessments of patient understanding during counseling of standardized patients. *Patient Educ Couns, 77*(1), 128-135. doi:10.1016/j.pec.2009.03.013
Filiatrault, F., & Désy, M. (2017). *Framework values ethical analysis public health actions.* Quebec, Canada. Retrieved from https://www.inspq.qc.ca/en/publications/2285
Frolic, A., Drolet, K., Bryanton, K., Caron, C., Cupido, C., Flaherty, B., . . . McCall, L. (2012). Opening the black box of ethics policy work: evaluating a covert practice. *Am J Bioeth, 12*(11), 3-15. doi:10.1080/15265161.2012.719263
Giacomini, M., Kenny, N., & DeJean, D. (2009). Ethics frameworks in Canadian health policies: foundation, scaffolding, or window dressing? *Health Policy, 89*(1), 58-71. doi:10.1016/j.healthpol.2008.04.010
Gilligan, C. (1982). *In a Different Voice: Psychological Theory and Women's Development*. Cambridge, Massachusetts, USA: Harvard University Press.
Grill, K., & Dawson, A. (2017). Ethical Frameworks in Public Health Decision-Making: Defending a Value-Based and Pluralist Approach. *Health Care Anal, 25*(4), 291-307. doi:10.1007/s10728-015-0299-6
Gruben, V. (2013). Women as Patients, Not Spare Parts: Examining the Relationship between the Physician and Women Egg Providers. *Canadian Journal of Women and the Law, 25*, 249-283.
Hammell, K. (2013). Client-centred occupational therapy in Canada: Refocusing on core values. *CAnadian Journal of Occupational Therapy, 80*(3), 141-149.
Hanson, J. (2008). Shared Decision Making: Have we missed the obvious. *Arch Intern Med, 168*(13), 1368-1370.
Health Canada. (2018-02-26). Canada's Health Care System. Retrieved from https://www.canada.ca/en/health-canada/services/health-care-system/reports-publications/health-care-system/canada.html#a3

Health Canada. (2017). *Towards a Strengthened Assisted Human Reproduction Act: A Consultation with Canadians on Key Policy Proposals*. Ottawa: Minister of Health
Held, V. (2005). *The Ethics of Care: Personal, Political, and Global*: Oxford University Press.
Hovey, R., & Apelian, N. (2007). Is our incapacity of conversation a serious barrier to person centred medicine. *The international Journal of Person Centered Medicine, 4*(1), 52-59.
Hudon, C., Fortin, M., Haggerty, J. L., Lambert, M., & Poitras, M. E. (2011). Measuring patients' perceptions of patient-centered care: a systematic review of tools for family medicine. *Ann Fam Med, 9*(2), 155-164. doi:10.1370/afm.1226
Ikemoto, L. (2016). Assisted Reproductive Technology Use among Neighbours: Commercialization Concerns in Canada and the United States, in the Global Context. In T. M. Lemmens, Cheryl; Lee, Ian B.; Lemmens, Trudo; Martin, Andrew Flavelle; Milne, Cheryl; Lee, Ian B. (Ed.), *Regulating creation: the law, ethics, and policy of assisted human reproduction* (pp. 253-273). Toronto, Ontario, Canada: University of Toronto Press.
Jones, M., & Salter, B. (2010). Proceeding carefully: assisted human reproduction policy in Canada. *Public Underst Sci, 19*(4), 420-434. doi:10.1177/0963662509104722
Kant, I., & Abbott, T. K. (1873). *Theory of ethics.* London: Longmans.
Krupat, E., Bru, R., Thom, D., & Azari, R. (2001). When Physicians and Patients Think Alike: Patient-Centered Beliefs and Their Impact on Satisfaction and Trust. *Journal of Family Practice, 50*(12), 1057-1062.
Laine, C., & Davidoff, F. (1996). Patient-centered Medicine. *JAMA, 275*(2), 152-156.
Lévesque, M., Hovey, R., & Bedos, C. (2013). Advancing patient-centered care through transformative educational leadership: a critical review of health care professional preparation for patient-centered care. *Journal of Healthcare Leadership, 5,* 35-46. doi:10.2147/jhl.S30889
Levinson, W., Gorawara-Bhat, R., & Lambs, J. (2000). A Study of Patient Clues and Physician Responses in Primary Care and Surgical Settings. *JAMA, 284*(8), 1021-1027.
Lusk, J., & Fater, K. (2013). A Concept Analysis of Patient-Centered Care. *Nursing Forum, 48*(2), 89-98.
Madore, O. (1991). *Established Programs Financing For Health Care*. Ottawa, ON, Canada. Retrieved from: http://publications.gc.ca/site/eng/9.561540/publication.html
McCormack, L. A., Treiman, K., Rupert, D., Williams-Piehota, P., Nadler, E., Arora, N. K., . . . Street, R. L., Jr. (2011). Measuring patient-centered communication in cancer care: a literature review and the development of a systematic approach. *Soc Sci Med, 72*(7), 1085-1095. doi:10.1016/j.socscimed.2011.01.020
McDougall, R. (2015). Reviewing Literature in Bioethics Research: Increasing Rigour in Non-Systematic Reviews. *Bioethics, 29*(7), 523-528. doi:10.1111/bioe.12149
Mead, N., & Bower, P. (2000). Patient-centredness: a conceptual framework and review of the empirical literature. *Social Sciences and Medicine, 51*, 1087-1110.
Meskill, D. (2013). Concepts and Consequences of Liberty: From Smith and Mill to Libertarian Paternalism. *Critical Review, 25*(1), 86-106. doi:10.1080/08913811.2013.823763
Mill, J. S. (1863). *Utilitarianism.* Kitchener, Ontario, Canada: Batoche Books.
Montori, V. M., Brito, J. P., & Murad, M. H. (2013). The optimal practice of evidence-based medicine: incorporating patient preferences in practice guidelines. *JAMA, 310*(23), 2503-2504. doi:10.1001/jama.2013.281422

Nelson, E. (2013). Global Trade and Assisted Reproductive Technologies: Regulatory Challenges in International Surrogacy. *Journal of Law, Medicine, and Ethics (Spring 2013)*, 240-254.
Nuffield Council on Bioethics. (2014). *An Ethical Framework.* London, England: Nuffield Council on Bioethics. Retrieved from: http://nuffieldbioethics.org/wp-content/uploads/2014/07/Public-health-ethical-issues.pdf
Noddings, N. (2002). *Starting At Home: Caring and Social Policy*. Berkley, California: University of California Press.
Norris, S., & Tiedemann, M. (2015). *Legal Status at the Federal Level of AHR in Canada* Ottawa, Ontario, Canada: Library of Parliament.
Ogden, J., Ambrose, L., Khadra, A., Manthri, S., Symons, L., Vass, A., & Williams, M. (2002). A questionnaire study of GPs' and patients' beliefs about the different components of patient centredness. *Patient Education and Counseling, 47*(3), 223-227. doi:10.1016/s0738-3991(01)00200-2
Petrini, C. (2010). Ethics-based public health policy? *Am J Public Health, 100*(2), 197-198. doi:10.2105/AJPH.2009.181511
Pettersen, T. (2011). The ethics of care: normative structures and empirical implications. *Health Care Anal, 19*(1), 51-64. doi:10.1007/s10728-010-0163-7
Public Health Agency of Canada. (2013-02-04). *Fertility.* Retrieved from https://www.canada.ca/en/public-health/services/fertility/fertility.html
Reynolds, A. (2009). Patient-centered Care. *Radiologic Technology, 81*(2), 133-147.
Robinson, F. (2011). *The Ethics of Care*. Philadelphia: Temple University Press.
Robinson, J. H., Callister, L. C., Berry, J. A., & Dearing, K. A. (2008). Patient-centered care and adherence: Definitions and applications to improve outcomes. *Journal of the American Academy of Nurse Practitioners, 20*(12), 600-607. doi:10.1111/j.1745-7599.2008.00360.x
Rosser, W. W., Colwill, J. M., Kasperski, J., & Wilson, L. (2011). Progress of Ontario's Family Health Team model: a patient-centered medical home. *Ann Fam Med, 9*(2), 165-171. doi:10.1370/afm.1228
Ruddick, S. (1980). Maternal Thinking. *Feminist Studies, 6*(2), 342-367.
Santana, M. J., Manalili, K., Jolley, R. J., Zelinsky, S., Quan, H., & Lu, M. (2018). How to practice person-centred care: A conceptual framework. *Health Expect, 21*(2), 429-440. doi:10.1111/hex.12640
Seavey, J., Aytur, S., & McGrath, R. (2014). *Health policy analysis: Framework and tools for success*. New York: Springer Publishing Company.
Sherwin, S. (1989). Feminist and Medical Ethics: Two Different Approaches to Contextual Ethics. *Hypatia, 4*(2), 57-72.
Sherwin, S. (1992). *No Longer Patient: Feminist ethics and health care.* Philadelphia: Temple University Press.
Sherwin, S. (2002). The Importance of Ontology for Feminist Policy making in the Realm of Reproductive Technology. *Canadian Journal of Philosophy, 32*, 273-295. doi:10.1080/00455091.2002.10717590
Smith, L. F. P. (2009). The role of primary care in infertility management. *Human Fertility, 6*(sup2), S9-S12. doi:10.1080/14647703123313691 73

Snow, D. (2013). The Judicialization of Assisted Reproductive Technology Policy in Canada: Decentralization, Medicalization, and Mandatory Regulation. *Canadian journal of law and society, 27*(02), 169-188. doi:10.3138/cjls.27.2.169

Stewart, M. (2001). Towards a Global Definition of Patient Centred Care: The Patient Should be the Judge of Patient Centred Care. *BMJ Open, 322*(7284), 444-445.

Taylor, M. G. (2009). Chapter 1: The 1945 Health Insurance Proposals: Policymaking for Post-war Canada. In Taylor, M. G (Ed.), *Health Insurance and Canadian Public Policy* (pp. 1-68). Montreal, Quebec, Canada: McGill-Queens University Press.

The College of Family Physicians of Canada. (2009). *Patient-Centred Primary Care in Canada: Bring it on Home.* Retrieved from: https://www.cfpc.ca/projectassets/templates/resource.aspx?id=890

Tronto, J. (1993). *Moral boundaries : A political argument for an ethic of care.* New York: Routledge.

Tronto, J. (2013). *Caring Democracy*. New York: NYU Press.

Verkerk, M. (2001). The care perspective and autonomy. *Medicine, Health Care and Philosophy, 4*, 289-294.

Weller, G. R., & Manga, P. (1983). The Development of Health Policy in Canada. In M. M. Atkinson & M. Chandler (Eds.), *The Politics of Canadian Public Policy,* (pp. 223-246). Toronto, Ontario, Canada: University of Toronto Press.

Wilkes, S., & Murdoch, A. (2012). Ovulation induction with clomifene: a primary care perspective. *J Fam Plann Reprod Health Care, 38*(1), 48-52. doi:10.1136/jfprhc-2011-0103

Wong, S., & Haggerty, J. (2013). Measuring Patient Experiences in Primary Health Care. Retrieved from Vancouver, British Columbia, Canada: www.chspr.ubc.ca

World Health Organization. (2007). People-Centred Health Care: A Policy Framework. Switzerland: World Health Organization. Retrieved from https://iris.wpro.who.int/handle/10665.1/5420

Zandbelt, L. C., Smets, E. M., Oort, F. J., Godfried, M. H., & de Haes, H. C. (2007). Patient participation in the medical specialist encounter: does physicians' patient-centred communication matter? *Patient Educ Couns, 65*(3), 396-406. doi:10.1016/j.pec.2006.09.011

Appendix 1

Table 10: Search Results for Chapter 3

Search #	Name of Database	Database time coverage	Date Searched	Number of records	Search strategy
1	Pubmed	All	June 28 2018	10 435	(((((((((ethics) OR ethical) OR moral) OR hospital ethics committee) OR ethics committee, clinical) OR guidelines as topics)) AND ((((((tool) OR method) OR stepwise tool) OR framework) OR instrument) OR guidelines)) AND ((((review) OR analysis) OR consultation) OR decision making)) AND ((health policy) OR healthcare policy)
2	Pubmed	All	June 28 2018	5831	((((((hospital ethics committee) OR ethics committee) OR guidelines as topics)) AND ((((((((tool) OR method) OR stepwise tool) OR framework) OR instrument) OR guidelines) OR evaluation)))) AND ((health policy) OR healthcare policy) AND ((((review) OR analysis) OR consultation) OR decision making)
3 (search terms adjusted	Pubmed	All	June 28 2018	45 (1 relevant)	((((Health Policy) OR Healthcare policy)) AND ((((("ethical/evaluative") OR "moral/ethical") OR "hospital ethic committee") OR "ethics committees, clinical")) AND (((((tool) OR instrument) OR "guidelines as topics") OR stepwise tool))
4	pubmed	All	June 28 2018	59 (2 relevant)	(((((((("ethical/evaluative") OR "moral/ethical") OR "ethics review") OR "hospital ethic committee") OR "ethics committees, clinical")) AND (("Health Policy") OR Healthcare policy)) AND (((((tool) OR instrument) OR "guidelines as topics") OR stepwise tool))
5	Scopus	All	June 29 2018	48 (1,	TITLE – ABS - KEY (ethical OR moral OR hospital AND ethics AND committee OR clinical AND ethics AND committee) AND (tool OR stepwise AND tool OR framework OR instrument) AND (analysis OR consultation OR decision AND making) AND TITLE-ABS-KEY (health AND policy OR healthcare AND policy)
6	EMBASE	1996-2018	June 29, 2018	194	(healthcare policy OR health policy)ab. AND (tool OR stepwise tool OR framework OR instrument OR guidelines).ab. AND (ethic* OR moral OR hospital ethics committee OR clinical ethics committee).ab.
7	EMBASE	1996-2018	June 29, 2018	86	[(healthcare policy OR health policy)ab. AND (tool OR stepwise tool OR framework OR

					instrument OR guidelines).ab. AND (ethic* OR moral OR hospital ethics committee OR clinical ethics committee).ab.] + (analysis or decision making or consultation).ab.
8	ETHXWEB		July 16 2018	6	ethical review of health policy - Title includes: Health policy
9	Cochrane	All Years	July 16, 2018	35	tool or instrument or framework or stepwise tool or guideline tool:ti,ab,kw and health policy:ti,ab,kw and review or analysis:ti,ab,kw and ethic* or moral or hospital ethics committee:ti,ab,kw (Word variations have been searched)
10	Reference list of Frolic et al. (2013)	n/a	July 16 2018	1 article	Kass (2001) – ethics framework for public health
11	Canadian Journal of Public Health (J)	All years	July 16 2018	26, 1 relevant	ethics policy review tools Cohen et al. (2016) – report of an equity focused health impact assessment of a proposed universal parent program in Manitoba
12	Ref. list of Cohen et al.	N/a	July 16 2018	1 relevant article	European Centre for Health Policy. Health Impact Assessment: Main Concepts and Suggested Approach. Gothenburg Consensus Paper. Brussels: WHO Regional Office for Europe, 1999. Available at: http://www.impactsante.ch/pdf/HIA_Gothenburg_consensus_paper_1999 (Accessed May 3, 2009).
13	HEC forum (J)	All years	July 17 2018	117	ethics policy review tools
14	Health Policy (J)	All	July 17 2018	7	Ethics review health policy tools
15	Web search: Alberta Health Network	All	July 18 2018	n/a	Ethics review health policy tools
16	Web search: PEI health	All	July 18 2018	n/a	Ethics review health policy tools
17	Web search: CIHR	All	July 18 2018	n/a	Ethics review health policy tools
18	Web search: Australian government	all	July 18 2018		Ethics review health policy tools

	department of health				
19	ProQuest Dissertation and Thesis Global	All years	July 19 2018	156 (2 saved)	ab(Healthcare policy OR health policy) AND ab(Ethics OR moral) AND ab(tools OR instrument OR framework OR stepwise tool) AND ab(review OR analysis)
20	Institut national de sante publique	All years	July 20 2019	17	Ethics analysis of policy Subject: ethics English or French
21	WHO European centre for health policy	All	July 23 2018	1260	ethical review of health policy
22	Reference list of Haynes et al. (2016)	n/a	July 23 2018	0 relevant	
23	Reference list for TOPHC 2015 (NCCHPP)	n/a	July 24 2018	1 relevant	Marckmann, G., Schmidt, H., Sofaer, N., & Strech, D. (2015). Putting public health ethics into practice: a systematic framework. Frontiers in public health, 3(23), 1-8.
24	Reference list for Marckmann et al. (2015)	n/a	July 24, 2018		Nieburg, P.; Gaare, R.; Bonnie, R. Ethics and practice of public health. In Law in Public Health Practice; Goodman, R., Rothstein, N., Hoffman, R., Lopez, W., Matthews, G., Eds.; Oxford University Press: Oxford and New York, UK and USA, 2003; pp. 43-62.
Meeting with librarian					
25	BELIT (bioethics literature database)	all	October 1, 2018	13	("Health Policy" OR "Healthcare policy") AND ("review committee" OR "analysis") AND ("Tool"OR "instrument" OR "Stepwise tool" OR "framework" OR "Guidelines tool") AND ("ethics" OR "ethical" OR "moral" OR "hospital ethics committee")
26	American Journal of Bioethics	All	October 1, 2018	217 (22 pages)	tools for ethical review of health policy
27	Lexis	All	October 2, 2018	42 Canadian Cases (not used because these are legal summaries)	("health policy" or "healthcare policy") and ("review" or "analysis") and ("tool" or "instrument" or "stepwise tool" or "guideline" or "framework") and ("ethics" or "ethical" or "moral" or "hospital ethics committee"))
28	McGill Journal of	All	October 2, 2018	18	ethical review health policy tools

	Law and Health				
29	McGill Journal of Law and Health	All	October 2, 2018	16	((((((("health policy" OR "healthcare policy") AND ("committee review" OR "analysis")) AND ("tool" OR "guideline" OR "framework" OR "stepwise tool")) AND ("ethical" OR "ethics" OR "moral" OR "hospital ethics committee")))) AND (volshortname:mcghealp)
30	Yale Journal of Health policy, law, and ethics	All	October 2, 2018	89	(((((((("health policy" OR "healthcare policy") AND ("committee review" OR "analysis")) AND ("tool" OR "guideline" OR "framework" OR "stepwise tool")) AND ("ethical" OR "ethics" OR "moral" OR "hospital ethics committee")) NOT ("research ethics")))) AND (volshortname:yjhple)

Appendix 2

Table 11: The adapted tool comprised of the Stewardship model and analyzing paternalistic policies

Tool(s)	Stewardship Model (*An Ethical Framework*, 2014) and Addressing Paternalism (Bellefleur & Keeling, 2018)
Steps	**Concerning goals, public health programmes should:** • **aim to reduce the risks of ill health that people might impose on each other;** • **aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing;** • **pay special attention to the health of children and other vulnerable people;** • **promote health not only by providing information and advice, but also with programmes to help people to overcome addictions and other unhealthy behaviours;** (not relevant here; excluded from review) • **aim to ensure that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise;** • **ensure that people have appropriate access to medical services; and** • **aim to reduce unfair health inequalities.**

	In terms of constraints, such programmes should: *4.* **not attempt to coerce adults to lead healthy lives;** *5.* **minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate;** *Is the policy actually paternalistic?* *• Does the policy actually interfere with the freedom of the individuals it is intended to help or protect?* *• If the policy interferes with the freedom of certain persons, were the latter involved in the process of developing the policy or intervention? Given their level of involvement and their opinions, can they be thought of as having consented to this interference?* • *With whom or what does the policy interfere? Citizens/consumers or businesses?* • *Who does the policy seek to protect? The persons with whom it interferes, other persons or society in general?* • *Who supports such protection and who opposes it?* • **seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values.**

Legend:

Bold: Originates from Stewardship model

Italicized: Originates from the analyzing paternalistic policies tool