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A Biomedical and Health Policy Analysis of Evidence-Based Therapeutic Abortion in Canada

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Abstract

Therapeutic Abortion (TA) is the medically-necessary termination of pregnancy due to maternal or fetal health complications. As a "wicked problem", TA involves multiple stakeholders with competing biomedical and political ideologies. This research paper synthesizes evidence-based biomedical and health policy literature relating to TA, thereby advancing the aims of reproductive justice by supporting women in making informed health decisions. Firstly, a biomedical literature investigation was conducted to identify international evidence-based abortion standards, according to pregnancy trimester. Secondly, a policy analysis utilizing the "3-I" framework was conducted to determine the ideas, interests, and institutions involved in accessing safe and equitable TA in Canada.

The biomedical literature investigation indicates the combination of mifepristone and misoprostol is the "gold standard" for the medical termination of pregnancy in first trimester; dilation and evacuation is the preferred method for second trimester surgical abortion; and mifepristone followed by misoprostol can induce third trimester labour and delivery of a stillborn. Moreover, polarized discourses regarding fetal personhood (ideas), anti-abortion lobbying efforts (interests), and the policy legacy of Canadian federalism (institutions) negatively affect access to safe and equitable abortions in Canada, by deterring the use of evidence-based abortion guidelines. As a result of the political context surrounding TA in Canada, the availability of internationally recognized, evidence-based abortion practices does not guarantee safe and equitable TA access. Consequently, inter-sectoral collaboration between biomedical and health policy professionals is recommended in order to establish and implement broadly accessible TA services in Canada.

Introduction

The Dahomey kingdom (1600-1900AD) is represented by modern-day Benin, a West-African country bordering Togo, Nigeria and Niger (Devereux, 1955). Similar to other primitive societies, native to China, India, Persia and Egypt, anthropological evidence reveals a rich history of Dahomeian maternal health practices (Devereux, 1955). For instance, Dahomenian practices state, "If a pregnant woman is ill, the fetus is formally tried, and if it is found guilty of having caused her illness, is aborted in order to cure the mother" (Devereux, 1955, p. 213). While anecdotal in nature, the Dahomenian abortion practices illustrate a unique framing of therapeutic abortion (TA), that is often lost in modern day discourses concerning the medically-necessary termination of pregnancy.

Defining Therapeutic Abortion

Therapeutic abortion is the pharmacological or surgical termination of pregnancy, due to maternal or fetal health complications (Heffner & Schust, 2014). As a medical practice, TA exists between polarizing pro-life and pro-choice ideologies. The extent to which TA is available and accessible within a given population is a manifestation of politics— the power to allocate resources based on ideological assumptions and understandings (Buse, Mays & Walt, 2012). Policies affecting the legal status and accessibility of TA reflect the ideologies present in a given society (Kumar, Hessini & Mitchell, 2009). Therefore, a holistic understanding of TA necessitates the merging of biomedical and political paradigms.

As a medical practice, TA is governed by evidence-based pharmacological and surgical procedures and techniques (WHO, 2014). Clinical trials inform best-practices, "gold-standards" of care, and internationally recognized protocols for women undergoing TA. However, ideologies of fetal personhood discredit TA as a medical procedure, by advocating for its legal

erasure and restricted accessibility (Cockrill & Nack, 2013). When personhood is understood to begin at conception, autonomy and individuality are granted to the fetus (Sherwin, 1991). Consequently, research and clinical practice relating to TA are tainted as immoral and equated with value-laden terms such as "murder" (Cockrill & Nack, 2013). Alternatively, by applying the established criteria of personhood solely to the woman, theorists have postulated that infanticide is acceptable, when the infant's life engenders the survival of an existing person, such as the mother (Warren, 1984). Ideologies of personhood create a polarized public discourse founded on the simplistic framing of abortion as an issue of preserving life or preserving choice (Herold, Kimport & Cockrill, 2015).

The Theoretical Framing of Therapeutic Abortion

The theoretical framework used to analyze TA in this paper rejects polarized pro-choice vs. pro-life discourses. Instead of describing the rights of the fetus as directly opposed to the rights of the mother, a relational and contextual framework of personhood will be utilized (Sherwin, 1991). A fetus develops throughout a pregnancy, which occurs during the lifespan of a particular woman, with a specific lived experience (Sherwin, 1991). Each gestating woman is imbedded in complex myriad of social and biological determinants of health, such as: genetics, socio-economic status, history of abuse, and access to health information. Thus, fetuses do not develop in generic wombs; fetal life is maintained within the context a woman's subjective physical and social experiences (Sherwin, 1991). In the absence of the woman, fetal personhood would cease to exist. Personhood cannot be contained within a set of criteria (i.e. consciousness, ability to communicate, reasoning, etc.) for it is a social category instead of an isolated state of being (Sherwin, 1991). As such, fetal personhood is relational, based upon the fetus' connection

to the woman's physical body and social context. Consequently, instead of being absolute, fetal personhood is relational and contextual, according to the fetus' biological connection to the woman (Sherwin, 1991).

The degree to which medicine has a duty of protection towards preserving fetal life will depend on the woman's subjective context. When the physical or mental wellbeing of the woman are at risk due to gestational complications, the fetus cannot claim ownership of the woman's body. While fetal personhood exists in relation to the woman, this interconnected relationship cannot jeopardize maternal health and wellbeing. In addition, it is up to the individual woman and her family unit to decide whether a major fetal anomaly merits TA. Ultimately, a relational framework of fetal personhood is the theoretical foundation from which TA will be further analyzed, bio-medically and politically.

Canadian Context

In 1969, Prime Minister Pierre Trudeau's Liberal government decriminalized TA access federally (Arthur, 1999). Access is defined broadly to include the access to internationally recognized, "gold-standard" abortion protocols, in addition to accessing appropriate evidence-based information pertaining to TA. Federally, Canadian abortion laws are not restrictive; however, access to TA varies by province. Provincial political ideologies restrict access to evidence-based abortion protocols pertaining to TA.

Thesis

This paper will synthesize evidence-based biomedical and health policy literature relating to TA. Firstly, evidence-based TA medical protocols will be presented by trimester of pregnancy. Secondly, a policy analysis using the "3I" framework will be utilized to determine the ideas, interests, and institutions that influence access to TA in Canada. Ultimately, this paper

demonstrates that internationally recognized, evidence-based abortion guidelines, do not guarantee safe and equitable TA access.

Part A: Biomedical Understanding of Abortion

Abortion: The Biomedical Procedure

Human gestation occurs over a span of 36 weeks, divided into three trimesters, each approximately 12 weeks in length. Abortion procedures differ firstly according to the duration of pregnancy. Secondly, abortions vary based on the procedure utilized to terminate the pregnancy. There are two main types of procedural abortions, the first of which is medical abortion—the termination of pregnancy through pharmacological agents, typically performed in the first trimester (<12 weeks), within a health care setting or the home (Kulier et al, 2011; WHO 2014). Medical abortion has been utilized worldwide since the 1970s, when prostaglandins and progesterone antagonists became available for biomedical use (Kulier et al, 2011). Secondly, Surgical abortion is the termination of pregnancy through the utilization of surgical instruments, typically performed within a health-care facility, during second trimester (>12 weeks) (Kurlier, et al, 2011; WHO 2014).

First Trimester Abortion (0-12 Weeks Gestation)

The first 12 weeks of pregnancy are represented by the first trimester. Typically, abortions occurring within the first trimester are performed medically (RCOG, 2015; WHO, 2014; WHO 2012). Within the first trimester, complete medical abortion occurs within hours or days, depending on the pharmacological agent used (WHO 2014). Generally, pre and post-medical abortion health care visits are required to ensure complete abortion has occurred (WHO, 2014). Gastrointestinal disturbances (nausea, vomiting, cramping) in addition to heavy bleeding (differentiated from hemorrhage) are common side effects (WHO 2014). To imitate the process

of miscarriage, the pharmacological agents may be administered alone or in combination (WHO, 2014). Progesterone antagonists, prostaglandins, and toxic trophoblastic compounds are the three main classes of pharmacological agents used during medical abortion (Kurlier et al, 2011). Specifically, the most extensively researched drugs are: mifepristone (progesterone antagonists), misoprostol (prostaglandin), and methotrexate (toxic trophoblastic agent) (Kurlier et al, 2011).

Mifepristone (RU-486): anti-progesterone. Mifepristone blocks progesterone receptors and increases the endometrium's sensitivity to prostaglandins (Kurlier, 2011). Decidualization is the post-ovulatory process of biochemical and morphological endometrial transformation, prior to implantation (Gellersen and Brosens, 2014). Elevated levels of the steroid hormone progesterone facilitates decidualization (Gellersen and Brosens, 2014). Within the uterus, progesterone relaxes the smooth muscle cells of the myometrium and maintains the decidual lining of the endometrium (Heffner and Schust, 2014). Implantation depends upon the decidua, which aids in burring the conceptus within the endometrium, thereby facilitating its gestational growth (Heffner and Schust, 2014). As a steroid progesterone antagonist, mifepristone results in the breakdown of maternal capillaries within the decidua, and increases prostaglandin synthesis within the endometrial glands (Kurlier et al, 2011).

When progesterone is withdrawn from the decidua, decidual necrosis ensues and the placenta is detached from the site of implantation. In the absence of decidualization, the products of conception cannot maintain implantation, and are eventually displaced from the endometrium (Kurlier et al, 2011). Essentially, mifepristone results in the detachment of the conceptus from the endometrial lining. An oral 200 mg table of mifepristone is administered orally throughout the first trimester (WHO 2012; WHO 2014). Following the ingestion of mifepristone, within 24-48h, a prostaglandin known as misoprostol, is administered orally, vaginally, buccally, or

sublingually (WHO 2012; WHO 2014).

Misoprostol: progesterone antagonist. Prostaglandins are hormone-like biological molecules that have widespread contractility effects on smooth muscle cells. Misoprostol is a prostaglandin analogue which activates prostaglandin receptors on gastric epithelial, parietal, and endometrial cells (Kurlier et al, 2011). Indicative of this fact, misoprostol induces cytoproctective effects on the gastric mucosa by reducing the secretion of HCl and pepsin (Vakil, 2016). Due to its effects on the gastrointestinal (GI) system, misoprostol is used to treat gastric and duodenal ulcers (Vakil, 2016). In fact, misoprostol is registered for the prevention and management of gastric ulcers (Kurlier et al, 2011). Misoprostol does not have a drug license for the use in pregnancy termination anywhere in the world (Dodd and Crowther, 2010). However, due to its strong uterotonic effects, misoprostol is also a powerful abortifacient and is used off label to terminate pregnancy (Kurlier et al, 2011).

The self-limiting effects of medical abortion are due to prostaglandin GI receptor activation. Gastrointestinal symptoms (nausea, vomiting, diarrhea, etc.) following medical abortion are due misoprostol's effects on the smooth muscles of the GI system. Relating to medical abortion, misoprostol softens the cervix and induces uterine contractions (Kurlier et al, 2011). The induced rhythmic uterine contractions will cause expulsion of the detached conceptus (Kurlier et al, 2011). The dosage of misoprostol depends on the route through which it is administered. The recommended dosage for vaginal, buccal or sublingual routes is 800 μg (WHO, 2012; WHO, 2014). Alternatively, 400 μg is the recommended oral administration of misoprostol (WHO, 2012; WHO, 2014). Oral administration of misoprostol is not recommended beyond 7 weeks' gestation (WHO, 2012; WHO, 2014). In addition, between 9-12 weeks' gestation, following the original 800 μg dosage administered vaginally, 400 μg of misoprostol is

given vaginally/sublingually every 3 hours, until expulsion occurs (WHO, 2012; WHO, 2014). A maximum of 4 doses of misoprostol is permitted in the latter case. (WHO, 2012; WHO, 2014). Conceptus expulsion typically occurs within 8-10 hours (WHO, 2014).

Combined regimen of mifepristone and misoprostol. The combination of mifepristone (anti-progesterone) and misoprostol (prostaglandin) induces complete abortion in 95% of pregnancies, if taken up to 63 days following amenorrhea (UKMT, 1990). In addition, there is strong biomedical evidence suggesting the use of mifepristone and misoprostol is safe and effective in terminating first trimester pregnancies, between 9-12 weeks' gestation (WHO, 2012). As such, the drug combination of mifepristone and misoprostol is considered the internationally recognized "gold standard" for the medical termination of first trimester pregnancy.

Despite WHO recommendations stating mifepristone followed by misoprostol is the most effective medical abortion protocol, this pharmacological combination is not approved for use in many countries (Dunn & Cook, 2014). While misoprostol (prostaglandin) can be used to induce uterine contractions off-label, mifepristone (progesterone-antagonist) is a highly regulated drug that remains to be approved in many countries (Dunn & Cook, 2014). In the absence of mifepristone, first trimester abortion can be induced through the off-label use of methotrexate (an existing chemotherapy drug) and misoprostol (Orrantia, 2017).

Methotrexate: a second class drug for abortion induction. Methotrexate is a folic acid antagonist that inhibits the DNA synthesis, thus acting as a cytotoxic trophoblastic agent (Kulier et al, 2011; Orrantia, 2017). In addition, methotrexate works directly on the trophoblast to block implantation (Chan, 2016). Repeated doses of methotrexate, as used in cancer treatment, affect the bone marrow, liver, and kidney function (Wiebe, 1997). However, a single dose of methotrexate exclusively targets trophoblastic purine and pyrimidine synthesis (Wiebe, 1997).

The prostaglandin misoprostol is administered 3-7 days after methotrexate, to induce the rhythmic uterine contractions that result in expulsion (Orrantia, 2017). Methotrexate is administered intramuscularly (Dunn & Cook, 2014; WHO, 2012). A 50mg/m^2 dosage of methotrexate followed 3-7 days later by 800 μg of vaginal misoprostol, induces complete abortion in 90% of pregnancies (WHO, 2012). Methotrexate is recommended for use in terminating pregnancies up to 7 weeks' gestation, proving to be more limited than the combination of misoprostol and mifepristone (Dunn & Cook, 2014). However, the toxicology subdivision of the WHO does not recommend methotrexate for medical abortion due to its teratogenicity, in the case of incomplete abortion (Dunn & Cook, 2014; WHO, 2012). Specifically, limb defects in addition to skull and facial abnormalities, have been recorded in the literature when incomplete abortion occurs (WHO, 2012).

Second Trimester Abortion (12-24 Weeks Gestation)

The second trimester of pregnancy begins following the 12th week of gestation, and terminates after the 24th week of gestation. Abortions performed in the second trimester account for 10-15% of all induced abortions worldwide (Lohr, Hayes & Gemzell-Danielsson, 2010). Delaying abortion until the second trimester may occur for a variety of reasons including: late diagnosis of fetal anomalies, fear of disclosure, and logistical/ financial barriers to accessing abortion services (Lohr, Hayes & Gemzell-Danielsson, 2010). Abortions in the second trimester may occur medically or surgically (WHO 2012; WHO 2014). When performed before the 16th week of gestation, surgical abortion is safer compared to child birth (Norwitz & Schorge, 2013). The surgical abortion technique that occurs early in the second trimester (12-14 weeks) is vacuum aspiration (WHO, 2014). Alternatively, the surgical abortion technique occurring later in the second trimester (>14weeks) is dilation and evacuation (WHO, 2014).

Vacuum aspiration (12-14 weeks). There are two types of vacuum aspiration. During manual vacuum aspiration, a soft, flexible, plastic cannula is attached to a self-locking, handheld syringe (aspirator), creating a vacuum (Norwitz & Schorge, 2013). Gestational age determines the appropriate diameter of the cannula (WHO, 2012). Upon dilation of the cervix, a cervical anesthetic is applied (WHO, 2014). The cannula is then inserted through the cervix; through repetitive rotating, in-and-out movements, the products of conception are evacuated into the attached syringe (Norwitz & Schorge, 2013). Vacuum aspiration is completed in a span of 3 to 10 minutes, on average (WHO, 2012).

Secondly, electric vacuum aspiration utilizes an electric pump to generate a vacuum (WHO, 2014). In addition, electric vacuum aspiration can accommodate a cannulae with a larger diameter, compared to manual vacuum aspiration (WHO, 2014). Upon cervical dilation and the application of a cervical anesthetic, a suction curette is inserted into the cervix toward the fundus of the uterus (Norwitz & Schorge, 2013). The electric vacuum applies suction to the curette, which is ten rotated 360 degrees, and withdrawn slowly to remove the products of conception (Norwitz & Schorge, 2013). Vacuum aspiration achieves complete abortion in 95%-100% of pregnancies (WHO, 2012).

Dilation and evacuation (>14 weeks). Due to advanced gestational age, dilation and evacuation may be performed in the operating room under general anaesthesia (Norwitz & Schorge, 2013). However, general anesthesia is not a medical requirement as it increases the risk of neurological damage; cervical anesthesia is the alternative (WHO, 2012). Dilation and evacuation is a combination of two surgical techniques—suction curettage, followed by manual evacuation (Casey, 2016). Ultrasound imaging may guide the physician in performing dilation and evacuation, however this is not essential (WHO, 2012). Suction curettage mechanically

destroys the products of conception (Norwitz & Schorge, 2013). Following suction curettage, manual evacuation removes the products of conception using specialized forceps (Norwitz & Schorge, 2013). The procedure is typically completed within 30 minutes (WHO, 2012). Dilation and evacuation does not increase the risk of subsequent miscarriage (Casey, 2016).

Medical abortion in the second trimester. Medical abortion is possible within the second trimester (WHO 2012; WHO 2014). However, surgical abortion is the preferred method beyond the threshold demarcating the first and second trimesters (Lohr, Hayes & Gemzell-Danielsson, 2010). Compared to surgical abortion, medical abortion in the second trimester is associated with greater: adverse GI effects, pain, complications such as haemorrhage and cervico-vaginal trauma, and greater incidence of overnight hospitalization (Lohr, Hayes & Gemzell-Danielsson, 2010). Thus, medical abortion in the second trimester is not superior to surgical abortion (Lohr, Hayes & Gemzell-Danielsson, 2010).

Similar to first trimester medical abortion, the pharmacological combination of mifepristone (progesterone antagonist) and misoprostol (prostaglandin), is used in second trimester medical abortion (WHO 2012; WHO 2014). As gestational age increases, uterine sensitivity to prostaglandins also increases (Wagaarachchi et al, 2002; WHO, 2014). Thus, there is an inverse relationship between gestational age and appropriate prostaglandin dosage. To induce medical abortion in the second trimester, mifepristone (200 mg) is administered orally, followed by 800 μg of misoprostol, vaginally (WHO, 2014). Every three hours, for a maximum of 5 doses, 400 μg of misoprostol is administered orally, then vaginally/ sublingually until the conceptus is expelled (WHO, 2014).

Third Trimester Termination of Pregnancy (24-36 weeks)

The third trimester marks the period between the end of the 24th week of gestation and birth. During the third trimester, pharmacological agents can induce labour, resulting in the birth of a stillborn (Dodd and Crowther, 2010). Third trimester pregnancies can be terminated in the rare case of intrauterine fetal death, and major fetal anomalies that are incompatible with life (Perritt, Burke and Edelman, 2013).

Intrauterine fetal death. Intrauterine fetal death may occur spontaneously, due to mechanical trauma, or may be the result of existing maternal health complications/ disorders such as hypertension (Wagaarachchi et al, 2002). In the case of fetal demise, over 90% of women will experience labour within three weeks of fetal death (Dodd and Crowther, 2010). Induction of labour and birth of a stillborn is recommended to decrease the risk of developing disseminated intravascular coagulopathy, emotional trauma, and to increase the usefulness of fetal autopsy (Dodd and Crowther, 2010; Wagaarachchi et al, 2002).

Medical Induction of Labour in the Third Trimester

Similar to first and second trimester medical abortions, mifepristone and misoprostol (alone or in combination) can be used to induce labour in the third trimester (Perritt, Burke & Edelman, 2013; Wagaarachchi et al, 2002). When labour is induced in the third trimester before the pregnancy is carried to term, the uterus is less sensitive to oxytocin (Wagaarachchi et al, 2002; Nakintu, 2001). Consequently, prostaglandins are used to induce labour in the third trimester (Wagaarachchi et al, 2002). However, since uterine sensitivity to prostaglandins increases with gestational age, prostaglandin levels utilized in first and second trimester medical abortions may not be appropriate for third trimester labour induction (Vayrynen, Heikinheimo & Nuutila, 2007; Wagaarachchi et al, 2002; WHO 2014). In fact, elevated prostaglandin levels

increase the likelihood of uterine tachysystole and hypertonicity (Wagaarachchi et al, 2002).

Evidence-based recommendations for the induction of labour in the third trimester are "based on limited or inconsistent scientific evidence" (Perritt, Burke and Edelman, 2013, p 347). Furthermore, there is no consensus regarding the recommended medical induction of labour in the third trimester, due to a limited number of controlled trials (Vayrynen, Heikinheimo and Nuutila, 2007; Wagaarachchi et al, 2002). The two regimens that appear in the literature are: (1) mifepristone followed by misoprostol and (2) misoprostol only, both of which are equally effective and safe (Vayrynen, Heikinheimo and Nuutila, 2007)

Part B: Policy Analysis of Medical Abortion in Canada

The pharmacological combination of mifepristone (progesterone-antagonist) and misoprostol (prostaglandin), is the internationally recognized, evidence-based protocol for medical abortion. Mifepristone has been legal in France, China, Sweden and the United Kingdom since the 1980s, and the US since 2000 (Dunn & Cook, 2014; Guilbert et al, 2016). In Canada, among the first cohort of women with legal access to TA since 1969, 31% had at least one abortion during their reproductive years (Norman, 2011). Furthermore, among this cohort of women, the median age at first abortion was 24 (Norman, 2011). This is say, nearly one in three Canadian women utilize abortion services within their reproductive life time. Since first trimester medical abortion represents the largest proportion of induced abortion in Canada (CIHI, 2013), the availability of mifepristone and misoprostol is fundamental to ensuring safe abortion access among the 31% Canadian women seeking abortion services.

Prior to 2016, Canadian women could not legally access the evidence-based medical abortion protocol of mifepristone and misoprostol because mifepristone was pending federal approval (Dunn & Cook, 2014). Health Canada approved the sale of mifegymiso in

July, 2015, for the purpose of terminating pregnancies up to seven weeks of gestation (Sheinfelf, Arnott, El-Haddad & Foster, 2016). Under the name of mifegymiso, 200 mg of Mifepristone and 800 μg of misoprostol have been approved for sale in Canada. However, the drug has been slow to integrate into clinical practice (Chan, 2016). The majority of hospitals and free standing clinics that offer first trimester medical abortion in Canada have yet to access the drug, under Health Canada's strict dispensation guidelines (Norman, 2016). In fact, as of February 2017, mifegymiso has been integrated into clinical practice in only three urban cities: Vancouver, Calgary, and Ottawa (McNight, 2017).

During the current phase of transition regarding the use mifegymiso, less than 4% of first trimester abortions in Canada are performed medically (Guilbert et al, 2016). In Canada, medical abortion is not widely used because the alternative to mifegymiso is methotrexate, a drug that is administered intramuscularly and not approved by the WHO for the termination of pregnancy (Dunn & Cook, 2014). However, over 85% of first trimester medical abortions in Canada utilize methotrexate (Guilbert et al, 2016). In addition, Canadian women are subject to invasive surgical abortion in the first trimester, where methotrexate is not available (Chan, 2016). Therefore, considering internationally recognized guidelines emphasize the use of mifepristone and misoprostol, Canada falls short of using evidence-based medical abortion protocol (Dunn & Cook, 2014). To further understand why this is the case, a policy analysis of the ideas, interests, and institutions of the stakeholders involved is provided.

Introduction to the 3I Framework

Policies concerning medical abortion fall under the scope of health policy, which exists within the larger category of public policy (Buse, Mays & Walt, 2012). Public policy is defined as, "a course of action or inaction chosen by public authorities to address a given problem or

interrelated set of problems" (Pal, 2013, p. 2). The failure to provide safe access to medical abortion through evidence-based protocol is a form of political inaction—a policy decision. The political actions or inactions of public authorities or policy actors are further understood through retrospective policy analysis. The qualitative policy analysis presented in this paper seeks to further understand why Canada has not implemented evidence-based medical abortion guidelines.

The 3I framework aims to explain public policy development according to the ideas and interests of policy actors, as well as the institutions in which they operate (NCCHPP, 2014). Firstly, ideas are beliefs regarding the current status of knowledge and research, views about ideal circumstances, or a combination of the two. Ideas impact the ways in which policy issues are framed and perceived by stakeholders. Ideas include information founded in scientific research in addition to dominant values specific to a given culture. Secondly, interests represent the political agenda of the stakeholders involved. For instance, the agendas of societal groups and elected officials are considered. Lastly, institutions are governmental structures that serve to shape or constrain policy decisions. Constitutions and past policies that shape political dynamics are termed policy legacies. Institutions create formal and informal norms that structure subsequent political behaviour (NCCHPP, 2014). Thus, the 3I framework can be utilized to analyze the interests, ideas, and institutions that affect access to evidence-based medical abortion guidelines.

Ideas. Fetal personhood is the predominant ideology that limits access to evidence-based abortion guidelines. Anti-abortion movements in Canada use fetal imagery as a strategy to discredit women who have terminated "innocent lives" (Kumar, Hessini and Mitchell, 2009). For instance, the Right to Life Association in Prince Edward Island (PEI) organizes demonstrations

in front of the Prince County Hospital (Ross, 2016). During such demonstrations, anti-abortion organizations utilize lobbying persuasion strategies that include verbally personifying the fetus (LifeCanada, 2016). Fetal personhood is rooted in the ideology that human life begins at conception, regardless of endometrial implantation (Fisher, 2013). Thus, under this line of reasoning, the fetus deserves protection because it is inherently human, possessing legal as well as moral rights (Fisher, 2013).

The ideology of fetal personhood beginning at conception, is contrary to Canada's legal and medical definitions of personhood (Fisher, 2013). According to the Criminal Code of Canada, "a child becomes a human being … when it has completely proceeded, in a living state, from the body of its mother, whether or not it has breathed, has independent circulation, or the navel string is severed" (Government of Canada, 2017). In addition, medically, the threshold of fetal viability occurs at approximately 23 weeks of gestation (Norwitz & Schorge, 2013). The medical threshold of viability is reflected in Canada's upper gestational abortion limit. In Canada, abortions are performed at a maximum gestational age of 23 weeks and 6 days, at British Columbia's Women's Hospital (ARCC, 2017). Thus, medical and legal knowledge concerning the threshold of viability and the legal status of the fetus, contradict ideologies of fetal personhood. However, ideologies of fetal personhood inform the political interests of anti-abortion lobbying groups.

Interests. In Canada, anti-abortion pressure groups are, "well-organized, well-funded networks including religious and political organizations" (Palley, 2006, p. 580). Specific anti-abortion groups include: United for the Family, Birthright, and the Coalition for Life (Palley, 2006). Such anti-abortion groups put political pressure to constrain the safe access and delivery of abortion services. Anti-abortion pressure groups are active in organizing pickets that block

entrances to abortion facilities, in addition to harassing women and their health care providers (Palley, 2006). The political agenda of anti-abortion pressure groups is to maintain the stigmatized status of abortion by negatively stereotyping women who obtain abortion services. Abortion stigma is a product of local actors and ideologies, rather than a universal truth that is constant across all contexts (Kumar, Hessini and Mitchell, 2009).

Stigma is defined as, "an attribute that extensively discredits an individual, reducing him or her from a whole and usual person to a tainted, discounted one" (Goffman, 1963, p. 3). The stigma associated with abortion, facilitated through anti-abortion picketing, marginalizes its medical practice and political advocacy (Cockrill & Hessini, 2015). Additionally, abortion stigma prevents the disclosure of women's abortion experiences, by perpetuating feelings of shame and judgement surrounding abortion narratives (Shellenberg et al, 2011). Furthermore, abortion stigma jeopardizes women's emotional health even in contexts with liberal abortion laws, such as Canada (Shellenberg et al, 2011).

The political agenda of abortion stigma masks the true frequency of abortion service utilization in Canada (Kumar, Hessini and Mitchell, 2009). Specifically, abortion stigma manifests itself through under reporting, which creates the misconception that abortion is an uncommon procedure (Kumar, Hessini and Mitchell, 2009). Stigma also associates promiscuity and irresponsibleness with the category of "women who abort" (Kumar, Hessini and Mitchell, 2009). Ultimately, abortion stigma undermines political actions advocating for increased access to abortion services (Kumar, Hessini and Mitchell, 2009). It is difficult for pro-abortion groups to mobilize the policy process due to current gaps in abortion epidemiological evidence. Anti-abortion picketing may be expected in increase as mifegymiso is integrated into pharmacies and primary care clinics across Canada. It is hypothesized that Canadian women's experience

utilizing and obtaining mifegymiso will be largely kept secret due to anti-abortion interests that perpetuate abortion stigma. Consequently, quantitative and qualitative evidence outlining barriers in accessing mifegymiso, will be difficult to obtain. Furthermore, the degree to which mifegymiso is implemented locally, is a manifestation of provincial autonomy.

Institutions. Federalism negatively affects the provincial delivery of abortion services (Palley, 2006). Governments typically fall under two systems—unitary or federal. Under a federal system, "the provincial level of government is not subordinate to the national government, but has substantial powers of its own which the national government cannot take away" (Buse, Mays & Walt, 2012, p. 85). The Constitution Acts of 1867 and 1982 set up a federalist relationship between the provincial and federal governments of Canada. Consequently, health care is the direct responsibility of each provincial government (Buse, Mays & Walt, 2012).

The Canada Health Act (1984) is a federal-provincial agreement that ensures reasonable access to medically-necessary physician services, across Canada (Kaposy, 2008). Furthermore, through the Canada Health money transfer, the act outlines federal monetary contributions toward provincial heath care funding (Kaposy, 2008). In order to receive full fiscal funding from the federal government, provinces must adhere to the principles of: portability, universality, comprehensiveness, accessibility, and public administration (Kaposy, 2008). Abortion access is an area of health policy where disagreements between provincial and federal governments occur, concerning the provision of medically-necessary services (Palley, 2006).

Therapeutic abortion and abortion at large, are considered medically-necessary services under the federal Canada Health Act (Palley, 2006). Therefore, provincially established access to abortion is necessary in upholding the Canada Health Act (Palley, 2006). As a result of

federalism, federal health policies are subordinated by the pressures and politics of provincial governments and pressure groups (Palley, 2006). Provinces have the autonomy to limit abortion access, thereby violating the Canada Health Act. Prince Edward Island (PEI) is a prime example of this. Until recently, for 34-years, PEI failed to provide abortion services, relying on abortions outsourced to New Brunswick and Nova Scotia (Nijhawan, 2016). The policy legacy of federalism affects the provincial implementation of mifegymiso. Despite federal Health Canada approval, local implementation implicates provincial cooperation. As a result of federalism, the legal approval of mifegymiso does not guarantee access to evidence-based abortion protocols. Thus, the slow integration of mifegymiso into provincial clinical practice is a manifestation of Canadian federalism.

Conclusion

This paper has synthesized biomedical and health policy frameworks in order to holistically analyze TA. Firstly, through the biomedical literature investigation, evidence based abortion protocols were investigated to understand current gynecological practice, as it relates to abortion. Abortions vary due to the gestational age at which they are performed and the means through which they are accomplished. Medical abortion, the termination of pregnancy through pharmacological agents, is used to terminate first trimester pregnancies (Kulier et al, 2007). Alternatively, surgical abortion, the termination of pregnancy by utilizing surgical instruments, is used to terminate second trimester pregnancies (Kulier et al, 2007). Regarding third trimester pregnancy termination, labour is induced to birth a stillborn (Dodd and Crowther, 2010).

Throughout the first, second, and third trimesters of pregnancy, the pharmacological combination of mifepristone (progesterone-antagonist) and misoprostol (prostaglandin) is used. Mifepristone and misoprostol result in medical abortion or the induction of labour by facilitating:

decidual necrosis, cervical softening, and rhythmic uterine contractions (Kulier et al, 2007). Therefore, mifepristone followed by misoprostol is the internally recognized, "gold standard" for abortion (WHO 2012; WHO 2014). Thus, the biomedical analysis reveals that TA can be conceptualized as a medical procedure, governed by cinical trials and evidence-based protocols.

However, the health policy analysis reveals that TA can also be conceptualized as a highly politicized and controversial practice in Canada. Since medicine is part of Canadian society at large, the extent to which TA is accessible according to biomedical standards of care, is a manifestation of politics. Thus, there is a striking contrast between objective abortion protocol governed by clinical trials, and anti-abortion lobbying efforts, rooted in the ideology of fetal personhood. The "3I" framework policy analysis revealed the ideas, interests and institutions involved in limiting access to mifegymiso in Canada. Fetal personhood, the policy agenda of abortion stigma, and Canadian federalism create a context in which the availability of biomedical research does not guarantee access to evidence-based abortion protocol. Canada's inadequate use of mifegymiso demonstrates biomedicine's limits in ensuring safe and equitable abortion access (Chan, 2016). Abortion access is a highly interdisciplinary field of study that cannot be adequately understood using a singular theoretical framework. Therapeutic abortion lies at the intersection of biomedical and health policy paradigms of knowledge. It is imperative that health care professionals and policy makers navigate both paradigms of knowledge when advocating for the clinical use of mifegymiso.

Therapeutic abortion access is not a modern biomedical or health policy issue. Accessing TA is debated worldwide and has been a controversial topic for centuries. However, what separates our modern society from primitive ones is the ability to develop evidence-based abortion protocols through biomedicine. Despite the perceived medical objectivity surrounding

established evidence-based abortion protocols, TA as a gynecological practice, continues to be marginalized and discredited. In this era of erasure regarding the gynecological practice of terminating pregnancy, primitive understandings of abortion become relevant. The Dahomey kingdom (1600-1900AD), far removed from the ability to conduct clinical trials, understood the positive role TA plays in maternal health and wellbeing (Devereux, 1976). By permitting abortion in case of jeopardized maternal health (Devereux, 1976), the Dahomey kingdom advanced the aims of reproductive justice in ways randomized controlled trials and evidence-based research cannot. The modernity of clinical trials and evidence-based policy create a false sense of objectivity surrounding the medical practice of abortion. Perhaps the people of Dahomey were far more advanced in their theoretical framing and conceptualization of TA.

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