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# Canadian Women Still Struggling with Access to Reproductive Care

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Matter Commented On: Federal and provincial barriers to medical abortion

Fifty years after Henry Morgentaler disregarded restrictive federal laws that limited access to abortion and opened his first clinic in Montreal, the health care system continues to fail women by not providing them with evidence-based reproductive care. This post will explore the barriers women face in accessing abortion services at the federal and provincial levels.

### **Evidence-Based Medical Abortion**

Women may terminate a pregnancy due to socio-economic reasons, because the pregnancy poses a threat to their physical or psychological health, or when the fetus is no viable or is likely to experience serious health complications. Although there are both surgical and medical options for abortion, many patients prefer the latter (see e.g. <a href="here">here</a> and <a href="here">here</a>) as it is less invasive than surgery, does not have the same risks as surgery (such as infection or puncture), does not require anesthesia, and can be completed in the privacy of one's home. Furthermore, medical abortions are more cost-effective than surgery and can facilitate access for women in <a href="rural locations">rural locations</a> without surgical facilities or specialists who are qualified to perform surgery. Despite its clear benefits, policy-makers have made it difficult for Canadian women to access safe and effective medical abortion.

The most effective pharmaceutical means of terminating a pregnancy is the combination of two products, mifepristone and misoprostol. While mifepristone impedes the action of progesterone (a hormone that is necessary to support pregnancy), misoprostol induces uterine contractions.

Although it is possible to terminate a pregnancy with misoprostol alone, the two-drug combination is significantly more effective. This efficacy is important because if the drugs are not successful, women must undergo surgery to complete the pregnancy termination. For example, a recent <u>study</u> in the New England Journal of Medicine compared the one and two drug regimes in women who had non-viable pregnancies between five and twelve weeks gestation. Pregnancy was effectively terminated in 83.8% of the patients who received both drugs, while misoprostol alone only worked 67.1% of the time. Other studies involving shorter gestation periods have found even higher efficacy rates for the two-drug combination. For example, researchers studying termination of pregnancies of up to seven weeks gestation found that using both drugs was effective in 96.7% of patients. The two-drug regime is recommended by the <u>World Health Organization</u>, the <u>American College of Obstetricians and Gynecologists</u>, and several other organizations and researchers (see e.g. <u>here</u>, <u>here</u>, and <u>here</u>).

Although Health Canada approved misoprostol <u>several decades ago</u> for the treatment of stomach ulcers, mifepristone was not available in Canada until 2017 and access barriers persist. In contrast, it has been <u>available</u> in France and China since 1988, the UK since 1991, most other European countries since 1999, and the US since 2000. In many European countries, the <u>percentage of patients</u> who receive medical rather than surgical abortion ranges from 60% to 90%. Mifepristone is <u>included</u> in the World Health Organization's Model List of Essential Medicines. It is shocking that Canada, a wealthy country with a well-developed health care system, does not provide access to all of the products on this list (including mifepristone), which represent the most effective and safe medications that meet the most important needs in a health care system.

# Health Canada as Passive Regulator

Mifepristone was initially unavailable in Canada because manufacturers failed to apply to Health Canada for its approval. This is likely due, in large part, to the high cost of regulatory approval relative to the minimal revenue generated by a drug with infrequent use (compared, for example, to drugs that manage conditions like high cholesterol or arthritis, which individuals may take daily for years or even decades). While Health Canada has programs to address financial barriers to the drug approval process (for example, for medicines that treat rare diseases), they have not taken steps to incentivize applications from manufacturers who produce reproductive medicines with public health importance (see e.g. <a href="here">here</a> and <a href="here">here</a> and <a href="here">here</a>).

Erdman argues that Health Canada has been perceived as having a bias towards reproductive medicine, which may have discouraged manufacturers from applying for the approval of mifepristone. For example, Health Canada did not approve a single contraceptive drug between 1994 and 2005 (despite many new products coming to market in other countries) and takes longer to approve these products than other types of drugs (see e.g. here, here, and here). This apparent bias towards reproductive medicine has persisted for decades, with Health Canada refusing in 2015 to approve a subdermal contraceptive implant that is more effective than oral contraceptives (as they are typically used) and has been approved in over 85 countries.

In short, while other governments have taken steps to facilitate access to mifepristone, Health Canada passively awaited an application from the manufacturer, while thousands of Canadian women were limited to surgical options or less effective medical means of terminating their pregnancies.

## Health Canada as Paternalistic Over-Regulator

A mifepristone manufacturer eventually applied for Health Canada approval, which was granted in 2015, with the product becoming available in 2017. Health Canada took two and a half years to approve mifepristone, which is approximately three times longer than new drugs ordinarily take. This approval time was particularly inordinate given the decades of safety data from the 60 other countries in which the drug was already available.

In addition, Health Canada placed an unprecedented number of restrictions on the drug (see <a href="here">here</a> and <a href="here">here</a>), which were unnecessarily paternalistic and severely limited its availability. For

example, unlike most drugs, prescribers had to register with the manufacturer and mifepristone could not be prescribed by nurse practitioners or dispensed by pharmacists to patients. Physicians had to complete special training to prescribe the product, which is an exceptional precaution normally reserved for drugs like methadone (a drug used to treat opioid addiction). These restrictions clearly acted as a deterrent, with many providers declining to jump through hoops to prescribe mifepristone. For example, in the first 18 months of the drug's availability, only 11.7% of OB/GYNs in Canada completed the requisite training. Even fewer family doctors and nurse practitioners (who may now prescribe the drug in some provinces) have completed the program. Of Canada's 89,911 physicians and 5,697 nurse practitioners, only 1.4% prescribed mifepristone as of September 2018.

In addition, until April 2019, an ultrasound was mandatory prior to a prescription for mifepristone, which severely restricted access for women in rural and remote locations or provinces with long waits for ultrasounds. Indeed, the Alberta government reported paying for only 39 medical abortions outside of Calgary or Edmonton between July 21, 2017 and June 28, 2018. A Globe and Mail investigation found that 73% of mifepristone prescriptions in Alberta came from a single clinic in Calgary (the Kensington Clinic). As long as abortion services are concentrated in urban areas, the reproductive liberty of rural women will not be realized.

Finally, Health Canada initially required that providers "supervise" patients taking the medication, which is normally only done in instances where doctors suspect drug diversion or misuse. One reproductive health researcher called this infantilizing policy "unnecessary and demeaning".

# **Inexplicable and Inequitable Provincial Funding Decisions**

Although the federal government regulates the approval of pharmaceuticals and monitors their safety, the provinces and territories are responsible for other drug-related matters such as funding. At the time of mifepristone's approval, all Canadian provinces funded surgical abortion, subject to restrictions in certain jurisdictions, such as New Brunswick's refusal to fund procedures performed outside of hospital (Province of New Brunswick v Morgentaler, 2009) NBCA 26). While surgical abortions cost provinces up to \$1500, a pack containing mifepristone / misoprostol costs approximately \$350. However, many provinces dragged their feet in insuring this safe and cost-effective drug, thereby essentially relegating many women to surgery and, in the case of rural patients, to considerable travel to obtain that surgery. For example, while Alberta insured mifepristone starting in July 2017, Saskatchewan and Manitoba did not provide universal public funding until June 2019.

### **Current Barriers to Access**

In 2017, the most recent year for which data is available and the year in which mifepristone became available, only 5.4% of abortions completed in Canadian hospitals were performed via medication rather than surgery. Of these women, only 0.7% received the more effective two drug regime.

Even as Health Canada's restrictions have been loosened and provinces have increased funding for medical abortion, access problems persist. For example, many doctors and clinics continue to rely on the less effective misoprostol-only treatment. While some practitioners may not realize that Health Canada has relaxed its burdensome restrictions, others may be merely continuing their practice of referring patients for mifepristone despite knowing they could now prescribe it without additional training and registration requirements. One Ontario reproductive health clinic reports that because so few family doctors prescribe mifepristone, patients often wait two to three weeks for an appointment. Because mifepristone can only be taken to terminate pregnancies of up to nine weeks gestation, this wait may disqualify women from using the medication, thereby leaving them no alternative but to have surgery. This wait may also have psychological consequences for patients.

### Conclusion

In 1988, the Supreme Court of Canada struck down an oppressive criminal regime that subjected women's reproductive choices to the approval of doctors and was characterized by delays that threatened their physical and psychological health (*R v Morgentaler*, 1988 CanLII 90). Although *Morgentaler* was heralded as a victory for reproductive rights, women continue to struggle to access reproductive health services. For various reasons, including patient preference, cost-effectiveness, privacy, and accessibility, medical abortion may be preferable to surgery. Yet policy-makers have failed Canadian women in ensuring that they have access to this safe and effective surgical alternative.

If Health Canada is to achieve its stated <u>mandate</u> of "ensur[ing] that high-quality health services are accessible", then it must proactively work with the manufacturers of reproductive medicines and products to ensure that Canadian women have access to these essential health services. Health Canada must also come up with measures to reduce its inordinately long approval process for reproductive products and ensure that restrictions on new drugs are evidence-based and reflective of the actual risk posed by those products.

At the provincial level, governments cannot continue to create financial barriers to care for women. In the case of a drug with considerable public health benefits, like mifepristone, provinces cannot passively leave its uptake to individual health facilities and practitioners. Instead, they must work with regional health authorities and colleges of physicians and surgeons to design programs to incentivize its uptake.

In *Morgentaler*, Justice Wilson stated that the result of the impugned legislative scheme was to "assert that the woman's capacity to reproduce is not subject to her own control", but rather is "subject to the control of the state", thereby intruding on her "right to personal autonomy in decision-making" (at 173). Although the state is no longer directly controlling the reproductive decisions of women through threat of criminal sanction, by limiting their reproductive choices and impeding access to evidence-based health services, federal and provincial policy-makers continue to perpetuate limits on reproductive autonomy.

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