Medication Abortion in Canada: A Right-to-Health Perspective

Joanna N. Erdman, JD, LLM, Amy Grenon, JD, and Leigh Harrison-Wilson, JD

The right to health under the International Covenant on Economic, Social, and Cultural Rights (ICESCR) entitles women to available, accessible, and acceptable abortion care. Abortion care in Canada currently falls short of this standard. Medication abortion (the use of drugs to terminate a pregnancy) could improve abortion care in Canada, but its potential remains unrealized.

This is in part attributable to the unavailability of mifepristone, the safest and most effective pharmaceutical for medication abortion. Given that it could improve abortion care, we investigated why mifepristone remains unapproved in Canada, whether its unavailability is attributable to government inaction, and whether Canada is therefore failing to fulfill its obligations under the right to health.

Abortion care and the International Human Right to Health

As a state party to the ICESCR, Canada recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” The right to health consists of an entitlement to the enjoyment of goods and services necessary for the realization of the highest attainable standard of health. This entitlement is reflected in Canadian health care policy, which seeks to protect, promote, and restore the physical and mental well-being of Canadian residents by facilitating their reasonable access to medically necessary health care without financial or other barriers.

Canada has further undertaken to implement the right to health without discrimination, including discrimination against women. A major burden of women’s ill health is related to reproduction, and reproductive health care is therefore identified as a priority obligation under the right to health. Realization of the highest attainable standard of health requires that women have the freedom to decide whether and when to reproduce and the right to health care necessary to effectuate their decisions.
Goods and services relating to pregnancy termination are important components of reproductive health care. The UN expert body that supervises state parties’ implementation of the right to health under the ICESCR has consistently advised state parties to review criminal laws on abortion because of their adverse consequences for women’s health.12–14

Abortion is a safe and effective intervention that serves important physical and mental health needs. Abortion terminates the unwanted physical state of pregnancy and avoids the physical and mental health risks of gestation, delivery, and postpartum recovery. Abortion also serves important non-medical ends, contributing to a woman’s broader social well-being.

Canadian law and policy recognize abortion as a component of reproductive health care. In 1995, the federal minister of health enacted a policy interpreting clinic abortion services as medically necessary,19 thereby requiring provinces to fund these services. In 2006, a Quebec court ordered the government to reimburse 45,000 women for out-of-pocket clinic expenses incurred for abortion services.16 In upholding the constitutionality of legislation regulating abortion clinic protest activity, a British Columbia court stated, “A woman’s right to access health care without unnecessary loss of privacy and dignity is no more than the right of every Canadian to access health care.”21

The right to health under the ICESCR requires that reproductive health care, including abortion-related goods and services, is available, accessible, and acceptable.10 Goods and services should be available in sufficient quantity; geographically and economically accessible to all women, in particular vulnerable and marginalized women; and delivered in a respectful manner. These interrelated features of the right to health—availability, accessibility, and acceptability—are the standard against which to assess abortion care in Canada.

ABORTION CARE IN CANADA

Since judicial decriminalization of abortion in 1988,18 induced abortion rates in Canada have exhibited a general decline.4 This trend may reflect a decline in unwanted pregnancies and thus in the need for abortion. It may also indicate a decline in the availability, accessibility, and acceptability of abortion care and thus a decline in health care necessary for the realization of women’s highest attainable standard of health. Two related factors support the latter interpretation. First, the availability and accessibility of surgical abortion facilities and providers are decreasing. Second, an acceptable method of medication abortion, an alternative to early term (within the first 9 weeks of gestation) surgical abortion, remains unavailable in Canada.

Surgical Abortion Facilities and Providers

The vast majority of early term abortions are surgically performed in hospital and clinic facilities. Although abortion is one of the most frequently performed of all surgical procedures,19 only select hospitals geographically distributed without reference to need perform the service. In hospitals in which services are formally available, access is often limited by quotas, referrals, and excessive delays.2,3 Six-week wait times for hospital abortions were recently reported in Ottawa, Ontario.20 Unreasonable wait times led to a constitutional challenge in Manitoba.21 Timely access to health care is an essential feature of the right to health.10

Excessive delay in hospital abortion care is often related to the unavailability of operating rooms and providers.22 Many hospitals, for example, lack willing and trained providers. Only half of all Canadian medical schools teach surgical abortion techniques, dedicating less than 1 hour of instruction to the subject in a 4-year curriculum.23 Surgical abortion training during obstetrics and gynecology residency is neither extensive nor mandatory, with only 20% of those trained providing abortions after residency.23 With an aging population of willing and trained providers, the availability of surgical abortion in Canada will likely continue to decline.

Lacking access to timely hospital services, women increasingly seek or are referred to abortion care in clinics. Between 1993 and 2004, the percentage of clinic abortions in Canada doubled from 23% to 46%.4 Clinics are perceived to offer care that is more comprehensive and supportive and of better quality than that received in hospitals. Clinic facilities, however, exist in only 8 of the 10 provinces and only in urban centers.5 The result of geographical disparity in the availability of hospital and clinic facilities is that many Canadian women must travel within or between provinces to obtain care. Travel often entails economic and personal costs. Women must schedule time off work, arrange for child care services, and pay out of pocket for travel, accommodation, and in many provinces, the service itself.5 Although some women value the increased privacy that may attend receiving abortion care outside their community, others are denied needed support from partners, family, and friends. Moreover, the associated costs of travel disproportionately affect vulnerable and marginalized women, contrary to the right to health standard.10

Medication Abortion

A decrease in the availability and accessibility of surgical abortion care is not necessarily an infringement of the right to health. This trend may indicate a fulfillment of the right to health if surgical abortion services are complemented by a more available, accessible, and acceptable method. Medication abortion represents such an alternative method.

Following pregnancy diagnosis and accurate gestational dating, women undergoing medication abortion first receive either mifepristone or methotrexate in a health facility and self-administer a different drug, misoprostol, at home after a set interval. The first drug interferes with the continuation of pregnancy. Misoprostol expels the products of conception from the uterus. Medication abortion occurs as a process over an extended period rather than as a
Medication abortion offers a different experience of abortion that may be more acceptable to and thus preferred by some women. Because no instruments are involved, many women describe a more natural experience, with their uterine pain resembling a miscarriage or menstrual cramps. Medication abortion may also be experienced as more private and respectful of the woman’s dignity and as generating a more egalitarian clinical interaction. The administration of mifepristone or methotrexate while the woman is dressed and the self-administration of misoprostol at home engender a feeling of greater control.

Many women, however, do not prefer medication abortion. Those who prefer surgical abortion cite uterine pain, the longer duration, and discomfort or fear about aborting at home without professional supervision as their reasons. Neither medication nor surgical abortion is thus the preferred method of all women seeking abortion. Research suggests, however, that when offered a choice between abortion methods, most women express a preference for one method. Acceptable care in the delivery of abortion services, including respect for a woman’s choice among equally safe and cost-effective methods, is an essential feature of the right to health.

Medication abortion could improve abortion care in Canada, but its potential remains unrealized. The number of medication abortions performed countrywide is difficult to assess, but it is estimated that only 1% to 2% of all abortions are pharmaceutically induced. One quarter of all abortions are performed within the first 9 weeks of gestation and are thus eligible for medication abortion. An even higher percentage might be eligible, because many women may request an abortion within the gestational limit for medication abortion but experience delays in receiving surgical abortion care. The question is thus, Why is medication abortion in Canada underused?

The Unrealized Potential of Mifepristone

Underutilization can be attributed in part to the unavailability of an acceptable method of medication abortion. Mifepristone, the safest and most effective pharmaceutical for medication abortion, has not been approved for use in Canada. Mifepristone is the only medicine indicated for early term pregnancy termination, and its combined use with misoprostol is the only medication abortion regimen recommended by the World Health Organization. As of 2007, 36 countries worldwide, including the United States and many European countries, have approved mifepristone for use in early pregnancy termination. In France, Scotland, and Sweden, more than half of eligible abortions are pharmaceutically induced with mifepristone.

In the vast majority of medication abortions in Canada, methotrexate (in an off-label use) is substituted for mifepristone in combination regimens. Methotrexate is registered in Canada for several indications, including the treatment of cancer, arthritis, and
activity of essential drugs as a core obligation under the right to health. In Canada, like all state signatories, is required to undertake measures, whether legislative, administrative, or budgetary, to ensure women's access to essential reproductive health medicines. In 2005, the World Health Organization added mifepristone and misoprostol to its Model List of Essential Medicines, thereby endorsing extensive research that the medicines are “effective, safe and convenient in inducing medical abortion until nine weeks of pregnancy.” The list is intended to guide governments in the selection of medicines that are essential for their population and that should thus be available in their health systems. The ultimate designation of medicines as essential remains, however, a national responsibility, to be determined by the priority health needs of a country’s population. A prime motivation in adding mifepristone and misoprostol to the list was decreasing abortion-related mortality in developing countries. Although abortion-related maternal death is not a priority concern in Canada, service delivery barriers to surgical abortion and the unacceptability of medication abortion with methotrexate create a public health need for mifepristone.

The International Right to Health Standard

In Canada today, the availability and accessibility of surgical abortion facilities and providers are decreasing, and an acceptable method of medication abortion is not available. Canadian women are denied enjoyment of reproductive health care necessary for the realization of the highest attainable standard of health. Abortion care in Canada may thus represent a failure of government to fulfill its international legal obligations under the right to health.

The failure lies not in the state of abortion care in Canada, but in government responsibility for this state. The ICESCR holds governments accountable for the state of health care. It does not require that a government immediately meet the standard of available, accessible, and acceptable health goods and services. There may be valid reasons why the standard cannot be immediately achieved. The right to health requires that government strive toward realization of this standard—undertaking legislative, administrative, and budgetary measures to ensure available, accessible, and acceptable health care—and to publicly account for its action or inaction.

Responsibility for Mifepristone’s Unavailability

Approval of medicines by the Federal Department of Health (Health Canada) is based on evidence of safety and efficacy. The World Health Organization Model List of Essential Medicines is authoritative evidence that use of mifepristone and misoprostol in pregnancy termination is both safe and cost effective. As early as 2003, the Society of Obstetricians and Gynaecologists of Canada noted the development, testing, approval, and medical acceptability of mifepristone in the United States, and several European countries supported its introduction into Canada for clinical use.

The unavailability of mifepristone in Canada cannot therefore be attributed to safety or efficacy concerns.

The unavailability of mifepristone is routinely attributed to the Canadian drug approval process, which can be initiated only by application from a pharmaceutical company. Mifepristone remains unapproved in Canada because Health Canada has received no application. Two barriers are commonly cited for this absence: financial incentive and political bias.

Financial Incentive

In many countries, medication abortion has proven less profitable than expected. In Canada, it is predicted that revenues will be moderate because of cost controls and will not offset high regulatory approval costs. Revenues from abortifacient medicines are expected to be lower than from other drug products because of their relatively infrequent use and the likelihood of negotiated pricing with public agencies and professional groups. Although Health Canada has sought to address financial barriers to drug approval applications through a cost-reduction program, its eligibility criteria target orphan drugs, medicines for rare diseases. No similar program addresses drugs that have public health importance but limited financial promise.

Health Canada also has procedures for priority review and approval of critical new drugs and breakthrough therapies. To obtain priority status, however, the drug must be intended for life-threatening or other serious conditions, and clinical trials must have demonstrated that it significantly increases efficacy or decreases risk compared with existing therapies. Given that medication abortion is neither safer nor more effective than surgical abortion and that access to existing interventions is not considered, mifepristone is unlikely to qualify for priority status.

Political Bias

Bias against reproductive health medicines, and especially abortifacient drugs, may also act as a strong disincentive for application. Health Canada has been perceived as biased against reproductive health medicines, largely because of stringent requirements for the approval of oral contraceptives. The requirements for approval of oral contraception in Canada as
compared with the United States and Europe have been described as onerous. 37 Between 1994 and 2005, Health Canada did not approve a single contraceptive formulation, despite many new products coming to market in other jurisdictions. 38 Recently approved oral contraceptives also took longer than the average new drug submission to navigate the premarket authorization process, despite demonstrated safe use in other jurisdictions. 37 According to a 2004 study, 11 of 12 contraceptive products approved for use in the United States, United Kingdom, Europe, and Australia in the preceding decade were unavailable in Canada “either because of Health Canada’s stricter requirements or because they are held up in the Canadian regulatory process.” 37(p499)

Government Inaction

Although Health Canada has not refused to approve mifepristone, neither has the government fulfilled its human rights obligations to ensure that this reproductive health medicine is available and accessible in Canada.

Health Canada programs to ensure access to unapproved drugs do little to increase access to medicines intended for public health benefit. Physicians must file an application for each patient to be considered individually. As a result of delays and costs associated with political opposition and stringent approval processes, the former patent holder of mifepristone adopted a corporate policy to submit the drug for approval only if invited to do so by a government official. 41

Applications for mifepristone worldwide have met with legal and political opposition as well as heightened scrutiny from public agencies. When mifepristone was approved in Switzerland, for example, a legal challenge (ultimately unsuccessful) was mounted to reverse the decision of the Inter-Cantonal Office for Control of Medicines. 39 In Luxembourg, the minister for health sought the opinion of a national advisory health and bioethics commission as part of the approval process. 40 As a result of delays and costs associated with political opposition and stringent approval processes, the former patent holder of mifepristone adopted a corporate policy to submit the drug for approval only if invited to do so by a government official. 41

The unavailability of mifepristone in Canada is partly attributable to government inaction, an unwillingness to enact measures to ensure Canadian women’s access to essential reproductive health medicines. Government action worldwide demonstrates the variety of measures that could be adopted in Canada. Direct government intervention, for example, facilitated mifepristone approval in the United Kingdom, Sweden, and the United States. In 1993, President Bill Clinton issued an executive memorandum directing the Food and Drug Administration and the Department of Health and Human Services to “promptly assess initiatives . . . [to] promote the testing, licensing, and manufacturing in the United States . . . [of] anti-progestins.” 45 In 1988, the French Ministry of Solidarity, Health, and Social Welfare ordered the patent holder of mifepristone to resume marketing and distribution of mifepristone under threat of compulsory licensing. The minister of health declared, “From the moment Government approval for the drug was granted, [mifepristone] became the moral property of women, not just the property of the drug company.” 46 As the French example demonstrates, drug approval alone is insufficient to ensure women’s access to medication abortion. Health system infrastructure must be developed, including insurance, education, and training, to ensure that when mifepristone is approved, it is accessible across Canada.

CONCLUSION

The unavailability of an acceptable method of medication abortion in Canada may be attributed to both corporate and government inaction. When pharmaceutical companies do not introduce safe and effective reproductive health medicines of significant public health benefit into the market for financial and political reasons, the right to health guaranteed by the ICESCR requires government action. By failing to facilitate the approval of mifepristone, given its potential to improve health care necessary to the realization of women’s highest attainable standard of health, Canada may be failing to fulfill its international human rights obligations.

About the Authors

At the time of the study, the authors were with the Health Equity and Law Clinic, Faculty of Law, University of Toronto, Ontario.
Requests for reprints should be sent to Joanna N. Erdman, JD, LLM, Faculty of Law, University of Toronto, 78 Queen’s Park, Toronto, Ontario, MSS 2C5, Canada (e-mail: joanna.erdman@utoronto.ca). This article was accepted June 13, 2008.

Contributors
J.N. Erdman originated the Health Equity and Law Clinic Project and supervised and contributed to the research, analysis, and writing of the article. A. Grenon and L. Harrison-Wilson each led the research and analysis for part of the article and contributed to writing the article.

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