Advancing reproductive health through policy-engaged research in abortion care

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Abstract

Mifepristone medication abortion was first approved in China and France more than 30 years ago and is now used in more than 60 countries worldwide. It is a highly safe and effective method that has the potential to increase population access to abortion in early pregnancy, closer to home. In both Canada and the US, the initial regulations for distribution, prescribing, and dispensing of mifepristone were highly restricted. However, in Canada, where mifepristone was made available in 2017, most restrictions on the medication were removed in the first year of its availability. The Canadian regulation of mifepristone as a normal prescription makes access possible in community primary care through a physician or nurse practitioner prescription, which any pharmacist can dispense. In this approach women decide when and where to take their medication. We explore how policy-maker-engaged research advanced reproductive health policy and facilitated this rapid change in Canada. We discuss the implications of these policy advances for self-management of abortion and demonstrate how in Canada patients “self-manage” components of the abortion process within a supportive health care system.

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Globally approximately half of all pregnancies are unintended and 60% of these will end in abortion.(1) However equitable access to abortion care remains a goal for many nations. The United Nations Committee on Civil and Political Rights has called for nations to decriminalize abortion, ensure that legal abortion be available to preserve a pregnant parent's life and health, and remove administrative or other barriers in the way of people seeking a legal abortion.(2) Mifepristone, first approved in China and France in 1988 and now used in more than 60 countries worldwide,(3) is an alternative to surgical abortion that can enhance equitable access. It is on the World Health Organization list of essential medicines,(4) and has an excellent safety and effectiveness profile demonstrated through administration to millions of people.(5–11) Until now, high-income country drug regulators have placed a range of restrictions on the distribution and administration of mifepristone.(12,13)

In Canada, abortion has been legal under defined conditions since 1969, and was entirely decriminalized in 1988. Abortion care has been available via universal free health care since 1969, and with guaranteed interprovincial coverage as of 2015, which means residents can access an abortion when traveling, working, or studying out-of-province but within Canada. Mifepristone is marketed in combination with misoprostol in Canada as Mifegymiso® for the indication of early medication abortion. It was made available in early 2017 with some prescribing and dispensing restrictions, which were removed by November 2017.[1] At that time Health Canada stated, "*In general, for most individuals looking at it from the outside,*

[1] The ultrasound requirement was removed by April 2019.

[mifepristone] is now being treated like any other medication."(14) This unique approach facilitated abortion access in primary care through a prescription by any physician or nurse practitioner, which could be dispensed by any pharmacist.(15) Community and primary care providers can deliver medication abortion care to patients through in-person or virtual visits, and support patients to take their medications at a time and place of their choosing, with ongoing access to health care providers as wanted or needed.(16–19)

The Canadian context provides a unique case study for advancing reproductive health and equitable access to abortion care. In Canada, patients "self-manage" components of the abortion process within a supportive health care system. In its 2022 abortion care guideline, the World Health Organization defined self-managed abortion as "self-management of the entire process of medication abortion or one or more of its component steps, such as self-assessment of eligibility for medication abortion, self-administration of medicines without the direct supervision of a health worker, and self-assessment of the success of the abortion process."(20) In Canada, "self-managed" medication abortion care is an extension of the health care system, for instance where it is prescribed by a health care provider virtually or in person and medication is taken at the time and place of the patient's choosing, with access to a trained health care provider when needed.(1,19,20) This model of care has the potential to address inequities in access to abortion by expanding the number and location of providers and making the process more convenient for patients.

In this commentary we explore the questions: What led to the removal of restrictions for mifepristone in Canada that had been barriers to distribution, prescribing, and dispensing? Are the factors that contributed to this regulatory change relevant for other nations where

abortion restrictions remain? What lessons can we learn from the Canadian health policy approaches to remove restrictions on mifepristone prescribing and dispensing?

Current Restrictions in Other Countries

The example of Canada's supportive regulatory and legal environment for abortion care stands in contrast to the situation in many comparable nations. Barriers to mifepristone access in high-income countries include explicitly restricting abortion provision to designated facilities or service providers, thereby limiting access in community-based primary care (New Zealand, Sweden, and United Kingdom), waiting periods for delivery of medication abortion (Belgium, France, US states), restrictions against provision of mifepristone by nurses and midwives (Australia), and other restrictive abortion legislation such as allowing it only in cases where there is foetal impairment, or where it will preserve the patient's health (Poland, US states, and others).(21–24)

In the USA, for instance, several provisions by the Food and Drug Administration (FDA) unnecessarily encumber mifepristone distribution and administration.(13,25) Although the FDA removed an "in-person dispensing requirement" to reduce burden and increase access during the COVID-19 pandemic, the regulations specify that a prescriber must be "certified" with the drug distributor prior to purchasing or prescribing the product; the dispensing pharmacy must be "certified"; and patients must sign a FDA-approved agreement form. Under these conditions, the drug may only be ordered by a health professional who has completed certification, which effectively interrupts the usual pharmaceutical supply and distribution systems. These restrictions likely contributed to the slow uptake of mifepristone medication abortion in the USA.(26) However, preliminary data from the Guttmacher

Institute indicates that, as of 2020, mifepristone medication abortion accounted for the majority (54%) of all US abortion, which is a sizable increase from 39% in 2017.(27) This increased availability may be attributed in part to evidence-based changes to how medication abortion is accessed, including in some US research settings via telehealth, or outside the formal health system, by physician assistants and nurse practitioners, and in clinics that provide medication abortion only, not surgical abortion.(27–30)

Requiring the prescriber to specifically 'certify' prior to prescribing impairs the uptake of this practice by primary care professionals and by general obstetrics and gynaecologists.(31) Such conditions could effectively limit this practice to high-volume sexual health and abortion clinics where prescribers may anticipate a certain volume of abortion care as worth the anticipatory investment to attain the certification. In Canada, the removal of federal restrictive measures, including certification, was followed by a rapid increase in uptake of medication abortion and in the number of abortion providers; within the first two years of mifepristone's availability in the province of Ontario, for instance, the proportion of all abortions provided medically increased from 2.2% to 31.4%, while the abortion rate remained stable.(32,33) While the number of higher volume abortion providers did not change, the majority of Ontario's new medication abortion prescribers offered fewer than 10 abortions per year, with a median of fewer than five abortions, and demonstration of no change in the safety of care.(32,33)

The requirement for pharmacist or pharmacy certification similarly impairs their likelihood of adopting the new practice of stocking and dispensing an unusual medication. In Canada when this requirement was initially put in place, this regulation ensured that pharmacists

across the country had to order directly from the pharmaceutical company rather than through their usual distribution systems and warehouses that deliver all other drugs to their pharmacy. As the supply chain logistics operators were not certified pharmacists/pharmacies, they were unable to include this medication in usual supply chain systems.(34) Thus, the condition to require both prescribers and dispensers to certify and to register with the pharmaceutical company perpetuates limited access to abortion in rural, remote, and smaller centres – areas where populations stand the most to benefit from widespread availability of mifepristone abortion.

Conversely, allowing any qualified health care professional to write a mifepristone prescription, which the patient is able to fill at any pharmacy, facilitates access and also offers other advantages. Pharmacists are highly trained health care providers, expert in managing and selling pharmaceuticals. Through their role, pharmacists in Canada offer contraception counselling and can prescribe emergency contraception.(35,36) Pharmacists can act as a 'bridge' to sexual and reproductive health clinics for patients at risk of unintended pregnancy.(37) When dispensing a prescription, pharmacists offer a therapeutic "double check", in addition to providing a second opportunity to answer patient questions about the therapy. Linked health administrative data are now a powerful resource to guide policy, system, and practice decisions; yet this data may not be collected via prescriber dispensing, as it is by pharmacists who, in many jurisdictions, routinely enter data on dispensed medication to health system databases.(38)

Timeline for Regulatory Change in Canada

Canada authorized mifepristone in July 2015, including a "Risk Management Plan" and "Restricted Distribution and Administration Program" similar to those implemented in the US and in Australia (see Table 1).(15) However, as the potential harms of these restrictions were discussed in the public sphere and at regulatory tables, and mifepristone was not available until January 10, 2017, many restrictions were removed within the first year of accessibility, before practice patterns became ensconced.(18) Although, in Canada, health service delivery is the responsibility of individual provinces and territories, the federal government has responsibility for drug approval. Specifically, the federal legislation for health service provision, the Canada Health Act (1985), describes the legal principles of health service delivery, including universality and comprehensiveness.(39) However, interpretation of the act and decisions on health policy and health services rests with the provinces and territories, and their respective health professional practice organizations.(40) This structure made it possible for a single federal entity, Health Canada, to make evidence-based changes to federal policies that restricted use of the medication abortion pill.

Factors Contributing to Policy Change in Canada

What are the factors that contributed to Canada's unique action to remove restrictions on the distribution and administration of mifepristone? Following Kingdon's classic "Multiple Streams Approach," a model that explains why some issues are addressed on the public policy agenda (41,42), we suggest that three "streams" of activity were essential to achieve this change: the recognition of a *problem* by those in or around government, the existence of a feasible alternative *proposal*, and a favorable *political* context (see Figure 1).

Recognition of the Problem

Prior to the availability of mifepristone, 96% of abortions in Canada were surgical, provided mainly in the largest cities within a hundred miles of the southern border, and the remaining 4% were medication abortions involving methotrexate and misoprostol.(43,44) In contrast, the proportion of reproductive age women who resided outside these cities ranged from 40-70% depending on the province.(44) Most (85%) of Canadians have a regular medical doctor (45), although access to a primary care provider can be limited in many areas, including urban settings. Those living in non-metropolitan areas often had to travel long distances to reach specialized abortion service facilities, leading to high out-of-pocket expenses.(46) Mifepristone abortion in primary care offers the potential to expand the number and distribution of abortion providers, and provide abortions closer to home.(47) Provision of abortion by primary care providers is highly acceptable in Canada where the majority of surgical abortion providers are specially-trained family physicians working in hospitals or outpatient abortion-specific facilities.(44) However, the initial restrictive measures for mifepristone presented significant challenges for primary care practitioners in community settings.

Recognizing that the regulatory approval of mifepristone could include conditions that posed challenges to the dissemination of mifepristone abortion practice into community primary care, our team of researchers of the Canadian national family planning research network (www.CART-GRAC.ca), along with clinician leaders, and advocates began to engage key stakeholders in 2014, before mifepristone approval. Discussions were held with the national professional organizations for family physicians, obstetrician/gynaecologists, and pharmacists. Each professional organization acknowledged that mifepristone practice would

be a core service appropriately provided by their members, and all three came together under the leadership of the Society of Obstetricians and Gynecologists of Canada (SOGC) to develop an evidence-based health professional training program and national clinical guidelines for medication abortion. Each organization released a statement the day mifepristone was approved, supporting the use of this medication by their members. The groundwork was thus laid prior to approval that could normalize mifepristone prescribing or dispensing as part of usual care. The Health Canada July 2015 mifepristone approval incorporated mandatory training to be delivered under the auspices of recognized health professional organizations (SOGC, College of Family Physicians of Canada (CFPC), and the Canadian Pharmacists Association (CphA)) rather than by abortion-specific organizations, a potential benefit to attract generalist practitioners to incorporate this new service into their practice. However, the approval conditions also introduced the restriction of physician-only prescribing and dispensing.

The April 2016 publication of a national study on mal-distribution of Canadian abortion services (38) and parallel media coverage (48) brought public attention to the restrictive prescribing and dispensing regulations. Over ensuing weeks, led by an editorial in the capital's leading paper, "*What was Ottawa thinking on the Abortion Pill?*" (49), all national newspapers, television news programs, and radio stations reported on the federal mifepristone regulatory decision, consistently critiquing them as cumbersome, paternalistic, or outside the jurisdiction of Health Canada.(48–51) While anti-choice sentiments were often acknowledged by media outlets, the overwhelming tone of the coverage was pro-choice and evidence-based. The minimal voice of anti-choice groups in the national conversation may be a reflection of the long-standing public majority support in Canada for

women's choice and women's rights, and together all of these may present reasons the strategies employed in Canada were met with such success.(52)

Creation of a Feasible Alternative Proposal

The proposed solution to the problem of inequitable abortion access was to facilitate the provision of mifepristone through primary care, by removing medically unnecessary restrictions on mandatory training, drug distribution, and administration.

The proposal emerged through strong collaborations between the researchers of CART-GRAC; the professional associations (SOGC, CPhA, CFPC and Canadian Nurses Association) and regulatory colleges responsible for health professional licensing of physicians, pharmacists, and nurses (the Colleges of Physicians and Surgeons, or of Pharmacists, or of Nurses respectively in each provincial jurisdiction); federal and provincial health ministries; and Health Canada. Iterative multilateral knowledge exchange was facilitated by federally funded research designed to detect and mitigate barriers to mifepristone implementation.(53) This coalition of "policy entrepreneurs" (41,42) provided a real-time stream of evidence that was shared and discussed among partners.(54)

The process to revise a drug product label typically begins with a "Supplement to a New Drug Submission" application by the manufacturer. Soon after the spring 2016 media controversy, the manufacturer and Health Canada began discussions toward this revised application, which was submitted December 5, 2016, with a decision announced November 7, 2017.(15)

Feasibility of this application was supported by mifepristone regulation changes in Australia and the USA. Analyses of the effects of the 2012 decision by Australia to permit pharmacists to dispense mifepristone directly to patients,(55) although limited in uptake by legal and process issues,(56,57) offered new evidence on safety not available at the time of the initial 2015 Canadian approval.(18) Similarly, 2016 FDA updates to the USA mifepristone label included: expanding gestational age limit to 70 days and revising language from "physician-only" to "health professional."(13,25) It was only in 2021, long after this process in Canada, and concurrent with emerging Canadian data on safety of direct to consumer pharmacist dispensing,(32) that the FDA allowed a certified pharmacy to dispense mifepristone directly to the patient.(25)

Jurisdiction for regulation of scope of practice for health professionals in Canada lies with provincial health professional licensing regulators, not with the federal food and drug regulator. Beginning in October 2016, health professional regulators in five provinces asserted their jurisdiction and announced to their licensed health professionals that despite the federal drug approval restrictions, a physician could write a prescription for mifepristone, and a pharmacist could dispense prescribed mifepristone directly to a patient.(33,58–63) The actions of provincial health professional licensing regulators to insist on change while openly defying the federal restriction, served to put the proposed solution into practice. There was no penalty for these actions which were supported by provincial laws; rather, they highlighted to federal decision makers that federal regulations had overstepped into areas of provincial jurisdiction, could inhibit the uptake of abortion practice, and could limit mifepristone's potential to improve abortion access.

The Political Context

The favorable political milieu during this period in Canada offered a "policy window" in which to reverse regulatory conditions on mifepristone; a convergence of the three Kingdon streams of problem, solution, and political context.(41) While mifepristone was approved July 2015 under a Conservative federal government, a few months later a Liberal government was elected with the promise to support equitable health care in rural areas;(64,65) and to ensure people in Canada have access to the full range of reproductive choices.(66) As the Prime Minister had noted while campaigning: "*It is not for any government to legislate what a woman chooses to do with her body*."(67)

This policy window was supported by current law. The Canadian Supreme Court holds that patients have the right to access an abortion without restrictions.(68) Abortion also is included in the list of services that all provinces must provide to be compliant with the *Canada Health Act,* federal legislation for Canada's publicly funded health services.(39,40) Pressure from the United Nations may have further contributed to political motivation to solve this problem. In their 2016 response to a Canadian government report, the United Nations *Committee on the Elimination of Discrimination against Women* urged the Government to improve equitable access to abortion services.(69)

Our collaboration of researchers, health professional organizations, and policy makers had the opportunity to present high quality evidence on a feasible solution to the limitations of the initial drug approval. We presented the evidence to federal decision makers who acknowledged a problem and were engaged in a process to review the conditions of drug approval, all while working within a favorable political context. These multiple factors and

actors – changes to Australia and USA mifepristone regulations, assertiveness of provincial health professional regulators, a change in the governing political party, and global pressure – contributed to create a policy window to address the issue of drug regulatory restrictions perpetuating inequitable access to abortion in Canada.

Impact of Changes on Abortion Access

Early evidence in Canada indicates that availability of mifepristone without restrictive measures contributed to several rapid improvements in access to medication abortion. Analysis of population-based administrative data from the province Ontario indicates that prior to the implementation of mifepristone in 2017 the percentage of abortions provided as medical procedures was 2.2%; in the period of November 2017 to March 2020, after restrictive measures were removed, the proportion of abortions provided medically increased to 31.4% and there was no material change in adverse events and complications.(32) These data offer compelling evidence that medication abortion can be prescribed and dispensed safely through normal pharmaceutical systems.

Medication abortion without restrictions also led to a substantial increase in the abortion workforce. In a national survey involving 465 abortion care providers completed from July-December 2020, the majority of respondents who provided first-trimester medication abortion in 2019 were primary care physicians (n=245, 63.1%), with less than five years' experience (n=223, 61.3%) who practiced outside of hospitals (n=228, 66.5%). Forty-three percent (n=165) practiced rurally. In contrast, in 2012 a similar survey identified fewer than 300 abortion providers across Canada, the vast majority of whom practiced in urban settings. In the province of Ontario, health administrative data revealed an increase in the

number of abortion providers within the first two years after mifepristone introduction but most markedly after removal of these restrictions.(33) Specifically, compared to the expected provider population rate based on the declining trend before mifepristone, the rate of health care professionals providing abortions nearly quadrupled from 11.8 to 44.3 per 100,000 female residents age 15-49 years within 2 years of mifepristone approval.(33) The removal of restrictive measures also created the conditions to support continued access to virtual abortion care when access to in-person health services was limited due to COVID-19 safety protocols. In a mixed methods survey of Canadian abortion providers investigating changes in access to Canadian abortion services since the COVID-19 pandemic, respondents in most Canadian provinces and territories reported an increase in the proportion of medication abortions provided compared with surgical abortion, and an increase in telemedicine.(70) Based on this emerging evidence base, we hypothesize that low- or no-touch medication abortion prescribed in primary care and dispensed by pharmacists may increase equitable geographic access to safe abortion care, potentially offering delivery of care in a closer-to-home, less stigmatized setting, reducing exposure and the fear of exposure to protestors often associated with purpose-specific abortion facilities.

What lessons can other jurisdictions learn from the Canadian experience?

The supportive political environment and removal of restrictions on medication abortion in Canada opened the door for mifepristone to be made available through normal prescribing and dispensing pathways in community and primary care. However, sweeping national changes did not guarantee access for all. Other factors – vocal champions, supportive interprofessional health provider networks, funding policies, and practice supports – were also critical across different levels of the health system to support uptake.(34,71) For

instance, while the national outlook for abortion access in Canada is positive, there remain jurisdictional barriers to access of mifepristone medication abortion in the province of Quebec. The College of physicians of Quebec (CMQ) continues to require several of the restrictions at a provincial level that Health Canada removed federally, including mandatory clinical training in surgical abortion before providing mifepristone, restricting nurse practitioners from autonomous practice by requiring them to prescribe under the supervision of a physician who performs abortions, and the requirement for a mandatory dating ultrasound.(72) These ongoing restrictions have dramatically slowed implementation of mifepristone in the province relative to the rest of Canada.(73–75)

Health policies to promote access to medication abortion health services may change in other jurisdictions. While there are current proposals to change abortion laws that would restrict or abolish abortion in some countries (US, Poland), we can foresee advances in many countries to decriminalize (South Korea, New Zealand, Ireland) or consider decriminalizing abortion (UK). As well, observing the effects of less restrictive practices initiated during the pandemic on equitable access to abortion care will provide the evidence needed to further eliminate unnecessary restrictions.(56,76–80) As Health Canada's decision was aided by the new data and experience in Australia and other jurisdictions, so too may new surveillance data from Canada (32) and other countries aid the deliberations of US or other regulators. Removing regulations for mifepristone is not a stand-alone solution to the problem of abortion access in high income nations. A host of other factors vary state by state, not least of which may be specific state or province-level restrictions on abortion that limit access.

Some key 'levers' may be adaptable for other settings, particularly where provinces and states have the right to make jurisdictional decisions about health services. For instance, the conflict of interest regulations in some Canadian provinces prohibit personal contact information of named trained prescribers to be provided to a drug manufacturer, although this was a requirement of the initial drug approval.(81) Federal regulators seemed unaware of, or initially ignored, these jurisdictional regulations; thus 'mobilizing' this knowledge was central to removal of the certification/registration system in Canada (54), and may be relevant in other jurisdictions where conflict of interest guidelines exist. Another key lever may be through regulation of health professional scope of practice, where licensing bodies at the state, territorial, and/or provincial level make decisions around how professionals engage in abortion care. For instance, in Canada, when mifepristone was first made available, some provincial regulators were early supporters for physicians and nurse practitioners to prescribe mifepristone and for pharmacists to directly dispense mifepristone to patients; this approach led to high uptake of mifepristone in primary care in British Columbia (54) and then Ontario. The inverse occurred through provincial-level restrictions in Quebec, where, although pharmacists' distribution was supported, regulatory decisions restricted mifepristone dispensing to physicians with surgical abortion training and ultrasound capacity, effectively curtailing the uptake of medical abortion in primary care.(73–75)

Finally, the Canadian medication abortion approval enables a model of care that facilitates self-managed medication abortion within a supportive health care system. The lack of restrictive measures made it possible to implement practice guidelines for a model of low or no touch medication abortion *within* clinical supervision and the support of the health care

system.(16) During early phase of the COVID-19 pandemic, the Society of Obstetricians and Gynaecologists of Canada adopted the position that medication abortion in Canada "*can be provided [in] a tiered approach (minimal resource, limited resource, and on-label provision with full resource utilization)*" and "*can safely be provided by telemedicine or virtual visits*," including through "no-touch" or "no-test" medication abortion regimens."(17) This means that different steps in the medication abortion patient care pathway can occur without in-person contact from a health care provider, effectively empowering individuals to self-manage abortion when, where, and if they choose.(82) Integrating self-managed medication abortion within clinical care, as has been demonstrated in Canada, enhances patient autonomy while maintaining safety.(29,83–85) By implementing the policies and measures that support self-managed medication abortion, jurisdictions can optimize the potential of this innovation while promoting autonomy, reproductive rights, and physical and emotional safety.(19,20,82)

Conclusions

Canada's policy changes that removed extraordinary restrictions on mifepristone distribution, prescribing and dispensing created a policy environment that supports better access to safe, early abortion care in primary care settings. The abortion-supportive political environment in Canada facilitated these changes through an openness to collaboration between researchers and policy makers, recognition of the importance of evidence-based health policy, and the inclusion of health professional regulators in advancing changes that reflect jurisdictional needs and practices. The Canada Health Act made it possible for a single federal entity, Health Canada, to make evidence-based changes to federal policies that restricted abortion, but also allowed the province of Quebec to apply restrictions on

delivery that limited access to medication abortion, an example which fortunately was not followed by other provinces. While Canada may still be struggling with provincial policy disparities limiting universal access to medication abortion, this bold step forward may assist other countries to improve access to safe, early, confidential abortion care.

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Table 1

Caption: Canadian Restricted Distribution and Administration and selected Risk Management Program measures by date instituted and date removed.[1,26,28-31†]

Notes: Registration of prescribers and pharmacists with the manufacturer was a condition instituted by the manufacturer, and approved by Health Canada. The requirement for pharmacists to complete training and register prior to ordering product was removed on 2017 May 17, and for all health care professionals it was removed on 2017 Nov 7.

Conditions of Use	Date instituted	Date removed
Direct observed dosing	2015 Jul 29	2016 Oct 16
Mandatory training for prescribers and pharmacists	2015 Jul 29	2017 May 17
Physician-only dispensing direct to the patient	2015 Jul 29	2017 Nov 7
Physician-only prescribing	2015 Jul 29	2017 Nov 7
Mandatory use of a manufacturer provided consent form to be signed by the patient	2015 Jul 29	2017 Nov 7
Registration of prescribers and pharmacists with the manufacturer, as a pre-condition to order product	2015 Jul 29	2017 May 17 2017 Nov 7

Figure 1

Caption: Multiple Streams Approach

Source/Notes: Adapted by the authors from Kingdon (1993, 2013). Three streams of activity are essential to achieve policy change: the recognition of a *problem* by those in or around government, the existence of a feasible alternative *proposal*, and a favorable *political* context.