PRE-PRINT AFM-503-19V2

Sarah Munro PhD,[1,2] Edith Guilbert MD MSc,[3] Marie-Soleil Wagner MD MS,[4] Elizabeth S. Wilcox MA,[2,5] Courtney Devane MSN,[6] Sheila Dunn MD MSc,[7,8] Melissa Brooks MD,[9] Judith A. Soon RPh,[10] Megan Mills MD,[11] Genevieve Leduc-Robert MSc,[11] Kate Wahl BSc,[5] Erik Zannier MD,[11] Wendy V. Norman MD MHSc[12,13]

Perspectives on factors influencing implementation of mifepristone medical abortion among Canadian physicians: a national qualitative study

Annals of Family Medicine, accepted February 2, 2020

1. Department of Obstetrics and Gynaecology, University of British Columbia
2. Centre for Health Evaluation and Outcome Sciences, Providence Health Care Research Institute
3. Department of Obstetrics and Gynaecology Laval University;
4. Department of Obstetrics and Gynaecology, University of Montreal
5. School of Population and Public Health, University of British Columbia
6. School of Nursing, University of British Columbia
7. Department of Family and Community Medicine, University of Toronto
8. Women's College Research Institute
9. Department of Obstetrics and Gynaecology, Dalhousie University
10. Faculty of Pharmaceutical Sciences, University of British Columbia
11. Faculty of Medicine, University of British Columbia
12. Department of Family Practice, University of British Columbia
13. Faculty of Public Health and Policy, London School of Hygiene & Tropical Medicine

Corresponding author

Wendy V. Norman, 320-5950 University Boulevard, Department of Family Practice, University of British Columbia, Vancouver, BC, Canada, V6T 1Z3, 604.875-2424 x4880, wendy.norman@ubc.ca

Sources of Support

Canadian Institutes of Health Research (PHE148161, CPP-329455-107837); Michael Smith Foundation for Health Research (Award #16743, #16603, 2012-5139 (HSR)); Society of Family Planning (SFPRF11-19).

Abstract

Purpose

Access to family planning health services in Canada has been historically inadequate and inequitable. A potential solution to access barriers appeared when Health Canada approved mifepristone, the gold standard for medical abortion, in July 2015. We sought to investigate the factors that influence successful initiation and ongoing provision of medical abortion services among Canadian health professionals, and how these factors relate to abortion policies, systems, and service access throughout Canada.

Methods

We conducted one-on-one semi-structured interviews with a national sample of abortion providing and non-providing physicians and health system stakeholders in Canadian health care settings. Our data collection, thematic analysis, and interpretation were guided by Diffusion of Innovation theory.

Results

We conducted interviews with 90 participants including rural practitioners and those with no previous abortion experience. In the course of our study, Health Canada removed mifepristone restrictions. Our results suggest that Health Canada's initial restrictions discouraged physicians from practice and were inconsistent with provincial licensing standards, thereby limiting patient access. Once de-regulated, remaining factors were primarily related to local and regional implementation processes. Participants held strong perceptions that mifepristone was the new standard of care for medical abortion in Canada and within the scope of primary care practice.

Conclusions

Health Canada's removal of mifepristone restrictions facilitated practitioners to implement abortion care in primary care settings. Our results are unique as Canada is the first country to facilitate provision of medical abortion in primary care through evidence-based deregulation of mifepristone.

Keywords

abortion, family planning, health policy, health services accessibility, implementation, qualitative research, interview

Perspectives on factors influencing implementation of mifepristone medical abortion among Canadian physicians: a national qualitative study

Introduction

Approximately 40% of pregnancies in Canada are unplanned and 1 in 3 Canadian women will have at least one abortion in their lifetime.[1–4] Access to health services in Canada that enable patients to plan and space their pregnancies has been historically inadequate and inequitable.[5] Prior to 2017 in Canada, abortion services were surgical and provided by fewer than 300 doctors at roughly 100 facilities in urban cities close to the Canada-US border.[4] In this context, patients who lived outside large cities had to travel significant distances to access abortion care.[6,7] Concern about these inequities was expressed in the November 2016 Report of the Committee on Elimination of Discrimination Against Women, where The United Nations Human Rights Commissioner called on the government of Canada to improve access.[5]

The approval of mifepristone medical abortion in July of 2015 by Health Canada (the equivalent of the U.S. Food and Drug Administration), appeared as a potential solution to improve abortion access in primary care settings.[8–10] Mifepristone became available for prescription by physicians in January 2017. Mifepristone is on the World Health Organization list of essential medicines[11] and is considered the "gold standard" for medical abortion. Mifepristone 200 mg oral and misoprostol 800 mg buccal/vaginal/sublingual is the regimen of choice for medical abortion up to 70 days among eligible women.[1] Data on use of mifepristone in other nations since 1988 suggests that the drug is associated with an increased proportion of medical abortion compared with surgical, but

not with an increase in overall abortion rates.[12] Health Canada's approval of mifepristone[9] included restrictions, such as mandated physician dispensing and registration with the manufacturer, that have contributed to low uptake of mifepristone in primary care in similar high-income nations, including the U.S.[10,12–15]

We hypothesized that Health Canada's restrictions would impede implementation of mifepristone in primary care.[16] We also anticipated that stakeholder-reported barriers and facilitators to implementation could inform improvements to Canadian abortion policy and practice. This study was part of a larger mixed methods investigation.[17] In the main study we sought to investigate: *What are the factors that influence successful initiation and ongoing provision of medical abortion services among health professionals, and how do these relate to health policies, systems, and services, and to abortion service access throughout Canada?* This paper focuses on the first question involving what factors influence initiation and provision of medical abortion, from the perspectives of Canadian physicians and stakeholders. Our research is a particularly novel contribution to the literature as Health Canada repealed its initial restrictions on mifepristone in 'real time' over the course our study – in October 2016, May 2017, November 2017, and August 2019 (see Box 1). These changes made it possible to prescribe and dispense mifepristone the same way as most other drugs in Canada. Our study will be relevant to other nations experiencing challenges with access to family planning services as Canada is the first to use evidence-based deregulation of mifepristone to facilitate provision of medical abortion in primary care settings.

Methods

Study Design

This national interview study aimed to explore factors that influence implementation of mifepristone in Canadian health service delivery and health systems. Our approach was guided by Rogers' Theory of the Diffusion of Innovation,[18] as articulated by Greenhalgh[19] and Cook.[20] This qualitative study was a component of a four-year prospective mixed-methods observational national program of research on factors that influence implementation of mifepristone in primary care, the CART-Mife Study (Contraception and Abortion Research Team-Mifepristone Study). A fulsome account of our methods and integrated knowledge translation[21] approach for the entire study can be found in our research protocol.[17] Our survey data collection is ongoing and not reported in the present study. Our approach was guided by the Standards for Reporting Implementation Studies statement.[22] Ethical approval was provided by the Behavioural Research Ethics Board of the University of British Columbia and BC Women's and Children's Hospital.

Setting

Our study took place in the context of Canadian health care settings, which we defined as any service delivery environment where a prescriber could provide primary care, including hospitals, abortion facilities, health centres, and private physician offices, as well as via telemedicine.

Participants

Following Greenhalgh's guidance,[19] we sought to interview potential adopters and representatives of organizations that had an interest or concern in implementation of the innovation, mifepristone. Individuals eligible to participate in interviews included: a) physicians who intended to begin

practice with mifepristone within the first year of availability; b) healthcare professionals, such as family physicians, who were eligible to become mifepristone prescribers but did not pursue this practice; and c) stakeholders who had the potential to impact health policy, system, and service factors that influence implementation of mifepristone (e.g. representatives of Health Canada, health care professional colleges, and advocacy groups). Participants had to be English- or French-speaking and reside in Canada at the time of the interview in order to participate.

Recruitment

For physicians who intended to begin practice with mifepristone within the first year of availability, we invited those who completed a CART-Mife Study national online survey between January and December 2017 and responded that they would like to participate in an interview. All interview invitations and a copy of the consent form were sent by email to potential participants. We invited non-providing health care professionals and stakeholders via third-party recruitment with the assistance of the study's knowledge user partners (e.g. health professional organizations). We also asked each non-providing physician if they would refer potential participants to the study (snowball recruitment). The potential study population was purposefully sampled to represent diversity of demographic characteristics (e.g., gender, age, profession, region), and factors related to implementation of mifepristone (e.g. previous abortion practice).

Our sampling, data collection and analysis were iterative, rather than linear, steps to collect sufficient data to illustrate the phenomenon of mifepristone implementation in Canada. As categories emerged from analysis of transcripts, we engaged in theoretical sampling which guided our invitation of physicians to participate in a repeat interview 12 months later. Our sampling for repeat interviews was guided by the question: Given our emerging understanding of the factors

that influence implementation, which participants would provide the most useful data to further develop those concepts? We invited physicians for repeat interviews that were likely to have information-rich cases of adoption or non-adoption. We also used stratified purposeful sampling (per above) to ensure that our repeat interview participants remained diverse and had varying experiences of abortion practice in the year following mifepristone availability.[23]

Data Collection

We developed and pilot tested our interview guide with a panel of researchers and clinicians prior to data collection (see Appendix 1). One-on-one semi-structured interviews were conducted by telephone in the first year of mifepristone availability at least 3 months after participants had completed training (April 2017 to December 2017). Repeat interviews were conducted one year later (October to December 2018). Three health services researchers (SM, EG, M-SW) conducted the interviews with support from a team of trainees from nursing, medicine, and population and public health (CD, MM, GL-R, KW, ESW, EZ). The trainees completed a full-day training workshop in the study procedures prior to engaging in data collection. During interviews, we sought to be attuned to the participants' comfort level, and differences in power and status. Data collection and analysis were concurrent. We conducted interviews until we achieved saturation: when new data repeated what was in previous data (in our data collection), themes were well exemplified in participant data (in our sampling), and no new themes emerged (in our analysis).[24,25] We also sought to recruit participants until our data sufficiently represented a range of the pre-identified factors from our purposeful sampling strategies. To ensure transparency and rigour, we engaged in verification strategies throughout, including constant comparison, keeping an audit trail, and sampling to theoretical sufficiency. All interviews were audio-recorded.

Data Analysis

Interviews were transcribed, and French interviews were translated to English, before two qualitative researchers (SM, ESW) subjected the data to thematic analysis, informed by Braun and Clarke's flexible approach.[26] We de-identified and coded a sample of transcripts independently and compared our results. Discrepancies were resolved through discussion with a third team member (WVN or EG). We developed a codebook inductively by identifying codes (themes) from the transcripts that were related to the research objectives and then mapped our themes to constructs in Diffusion of Innovation theory. We then explored individual, organizational, and system patterns, relationships, and interactions between the codes. To explain physicians' implementation behaviour, we considered the frequency of themes across the data, presence of conflicting themes, and perceived relevance of the themes. Finally, we wrote the analysis into a descriptive, explanatory narrative that illuminated the factors influencing implementation of mifepristone abortion practice.

Results

We conducted one-on-one interviews with health care professionals (n=55) and stakeholders (n=35) involved in the planning and provision of abortion services in Canada. We conducted repeat interviews with 27 of the 55 health care professionals at least 12 months after their initial interview, to explore experiences of mifepristone provision. All 90 participants were volunteers and all who consented to participate completed their interview (see Table 1). Among those who had provided abortions prior to mifepristone's availability, the experiences were diverse and ranged from writing one prescription for methotrexate-misoprostol to full-time surgical abortion practice.

Participants' perceptions of barriers and facilitators to implementation of mifepristone in routine primary care involved four over-arching themes informed by Diffusion of Innovation theory: 1)

Federal restrictions made mifepristone "more complicated than it needs to be"; 2) Navigating the "huge bureaucratic process" of organizational implementation; 3) Challenges with diffusion and dissemination of policy information; and 4) Adoption by individuals: "a process rather than an event". Themes and representative quotations are provided in Appendix 2.

1. Health Canada made mifepristone "more complicated than it needs to be"

Participants' interviews illuminated how Health Canada's initial restrictions influenced their ability to implement the innovation, mifepristone, in routine care. In the first year of mifepristone availability (2017), all of Health Canada's regulations for distribution of mifepristone were perceived to create unfeasible task issues that limited adoption of mifepristone abortion and in turn limited equitable access. While participants valued the knowledge from the online training modules, they also perceived training to be time-consuming and the registration with the manufacturer to be a breach of their privacy. Participants hypothesized that these factors would discourage other physicians from practice and thereby "*limit women's access to medications*" (006_Phys – family physician, Territories, previous medical and surgical abortion experience).

New prescribers with limited prior abortion experience emphasized that the initial requirement for physician-only dispensing of mifepristone was inconsistent with their scope of practice and that in their experience dispensing was the responsibility of pharmacists. One noted, "*I would definitely not have done this had they stuck to the original rules where we had to purchase, store all the products*" (011_Phys – family physician, rural British Columbia, previous medical and surgical abortion experience). The requirement for ultrasound to be used for gestational age dating and to rule out ectopic pregnancy limited the ability of clinicians to provide mifepristone where they felt their local access to timely ultrasound was challenging. In contrast, those working in established abortion

facilities perceived it to be an easy transition to prescribe mifepristone due to existing infrastructure, billing mechanisms, and skilled counselors.

Participants were unanimous in their criticism of an initial requirement that mifepristone be a directly observed dosing, as one participant clarified, "*I can't think of a safety reason that is more significant for that medication than it is for tons of other things that are prescribed and taken at or from a pharmacy*" (013_Phys – family physician, urban British Columbia, no previous abortion experience). This restriction was perceived as a paternalistic barrier to patient access, rather than a factor directly influencing clinician uptake. Although it remained in the product monograph initially, Health Canada removed this restriction before mifepristone became available in January 2017.[27] In spite of this early policy change prior to the start of our study, a number of participants misbelieved that they had to observe their patients take the drug.

2. Navigating the "huge bureaucratic process" of organizational implementation

The majority of Health Canada's federal restrictions were removed within the first year of availability (January-November 2017). Participants perceived that the "de-regulated" mifepristone regimen was simple and compatible with their primary care practice. However participants described persistent organizational barriers to implementing mifepristone in their local setting. Funding was a key challenge and included provincial variation in patient subsidies for the cost of the drug and in physician billing codes. Unequal costs and compensation across Canada created what participants described as a two-tiered system, where patients had financial access to surgical and medical options within one province, but in another they could face out-of-pocket charges only for medical abortion. Physicians described encountering "*a huge bureaucratic process,*" such as

adding the billing code for medical abortion to their payment system, before they could begin to prescribe mifepristone (003_Phys – family physician, urban Ontario, previous medical and surgical abortion experience).

Conscientious objection and anti-choice attitudes in organizations actively prevented physicians from implementing mifepristone abortion. Participants described hospital staff who refused to clean clinic rooms where abortion care was provided, hospital administrators who ignored requests to implement a medical abortion protocol, and community pharmacists who refused to dispense. These attitudes contributed to geographic variation in implementation of mifepristone.

Experiences of stigma and harassment from the general public were uncommon: "*it's not like we have people demonstrating outside the hospital or clinic about abortions. It's not to that degree. It's more just the obstruction caused by people's personal views*" (040_Phys – family physician, rural British Columbia, previous medical abortion experience). While this did not impact participants' willingness to implement mifepristone, it did influence how much they were willing to communicate or advertise their services as an abortion provider. To avoid scrutiny, some physicians chose to "*do it kind of in the dark*" and not to disclose their practice to family, friends, and colleagues (004_Phys – family physician, urban Ontario, no previous abortion experience).

While universal coverage for mifepristone was established in Quebec during the first year of mifepristone's availability in Canada, a separate policy process contributed an additional year of delay in making it available in this province. In addition, the Quebec College of Physicians added its own restriction requiring accredited training in surgical abortion for any mifepristone provider. While some participants felt that Quebec professional colleges were being unnecessarily restrictive (022_Stakeholder – national advocate), others reflected that Quebec's challenges may have been

mitigated if Health Canada had collaborated early on with provincial colleges to understand how regulations differed across provinces and territories (E8_Stakeholder & E9_Stakeholder – Quebec college/regulatory body decision makers).

Participants reflected positively on the examples set by British Columbia and Ontario, provinces where professional colleges of pharmacy and medicine chose to overrule Health Canada's restrictions soon after mifepristone's approval and to allow pharmacists to dispense directly to patients. Participants perceived that the actions in BC and Ontario increased access and safety by supporting "*doctors [to] do what they want using their own best medical discretion*" (022_Stakeholder – national advocate). Participants described how such actions emboldened health professional regulators in other provinces to follow suit and ease restrictions on mifepristone dispensing.

In rural communities, prescribers spoke about the realities of caring for patients who were distributed across vast geographic catchments and faced overwhelming barriers to access all primary care services, not just abortion. Some participants felt that it would be more feasible and private for many rural patients to access a single surgical abortion appointment compared to the multiple visits required for mifepristone medical abortion. Concerns about loss to follow-up for post-abortion care were strong for some participants. As one participant reflected, surgical abortion "*is more certain. They make one trip to the city. It's a done deal. They go home. They don't have to follow up*" (002_Stakeholder – advocate, Prairie province). Participants who were not concerned about potential complications said that having a "*sounding board"* of support from expert colleagues helped to assuage their fears.

In spite of these implementation barriers at the organization level, prescribers felt that the tasks involved in providing mifepristone were relatively simple, compatible with their practice, and easy to learn through self-study. For instance, one prescriber who had never provided abortion before, was surprised at how straightforward it was and recalled thinking, "*That was so crazy easy*" (034_Phys – rural family physician, Atlantic province, no previous abortion experience).

3. Challenges with diffusion and dissemination of policy information

During the first year of availability, as Health Canada removed restrictions, participants struggled to make sense of rapidly changing and inconsistent information about the shifting regulations:

> *"It seems almost every week there's a new announcement about some kind of change in funding or regulation or all this sort of stuff that makes it very difficult as a provider to know what you can and can't do. I actually think I don't know why it has been rolled out this way, but I think it's been made way more complicated than it needs to be."* (017_Phys – family physician, urban Ontario, previous medical and surgical abortion experience)

Participants described how a regulatory change would be reported in the news media, but the product monograph would remain unchanged on existing stock. As one physician from urban Ontario reflected in the summer of the first year of mifepristone availability, "*Is the pharmacist supposed to observe them taking the medication? Am I supposed to have the medication delivered to my office and then the patient come back? I don't actually, really, understand what the rule is there*" (022_Phys – family physician, urban Ontario, previous medical abortion experience). Having peers on hand to act as "*a sounding board"* was critical, particularly for rural prescribers (040_Phys – family physician, rural British Columbia, previous medical abortion experience). This confusion was

still present in repeat interviews conducted with participants in the year after mifepristone was de-regulated.

Participants who were members of the community of practice component of our main study, the Canadian Abortion Providers Support (CAPS),[28] consistently cited the platform's bi-weekly emails as a reliable source of information on changing regulations. Nonetheless, participants expressed a need for more public communication about mifepristone as a new standard of care for family physicians to raise awareness among both practitioners and the public. These attitudes often were intertwined with the belief that these practitioners had a "*responsibility"* to support access to reproductive care (012_Stakeholder – advocate, Prairies).

4. Adoption by individuals: 'A process rather than an event'

Following Diffusion of Innovation theory, "adoption is a process rather than an event, with different concerns being dominant at different stages."[19] Factors related to individual physician behaviour – such as ability, skills, and motivation – influenced implementation of mifepristone in routine care. Pre-adoption, physicians first had to be aware of mifepristone, have up-to-date information about Health Canada's changes, and have a clear perspective of how it would benefit their practice and patient population. During early use, participants' confidence in prescribing increased as they honed their skills and knowledge with each successful abortion. One described how this led in turn to increasing the percentage of medical versus surgical abortions at their clinic:

> "*Well, [the benefit] is already apparent to us. We have seen it on 250 patients thus far. That is more than we would see in an entire year when we were using methotrexate … Just seeing that, for those of us who have been around for as long as I have, it is a bit jaw dropping how well it*

works. It makes me even angrier that it took this long to get, that women were denied this for so long." (003_Stakeholder – facility leader, Prairie province)

One key facilitator was participants' perception of the 'relative advantage' of mifepristone in comparison to methotrexate medical abortion. They perceived that mifepristone was a more effective, reliable, and safe treatment. It also was seen to enhance access by allowing patients to manage their abortion in "*their home at their convenience"* (019_Stakeholder – advocate, British Columbia) and through primary care: "*I think it puts access into family doctor's hands because it's a lot more within our realm than going on and doing training in surgical abortions*" (004_Phys– family physician, urban Ontario, no previous abortion experience). Our repeat interviews with participants suggested providing even one medical abortion strengthened these attitudes.

Participants viewed mifepristone as the new best practice for medical abortion in Canada, which was a motivator to start providing. As one family physician reflected, "*Like I said, it's the standard of care for the physicians*" (038_Phys – family physician, rural British Columbia, no previous abortion experience). Our repeat interviews indicated that many family physicians in the sample became motivated to provide mifepristone after getting a well-timed nudge, such as counselling a patient with an unplanned pregnancy or hearing a colleague's experience of prescribing. However, a sample of urban physicians who did not yet prescribe mifepristone expressed that they were experiencing "*inertia"* (042_Phys – family physician, urban British Columbia, previous medical abortion experience) and would prefer the convenience of continuing to refer their patients to nearby abortion clinics. For these non-prescribers, the key pre-adoption barrier was a perception that abortion was already accessible in their urban community.

Discussion

Main Findings

We undertook a national qualitative investigation of physicians' and stakeholders' perceptions of the factors influencing implementation of mifepristone medical abortion during its first two years of availability in Canada. Our results indicate that uptake was initially challenging due to restrictions contained in federal approval of mifepristone; however within the first year of availability (January-November 2017) these restrictions were removed and mifepristone could be prescribed in primary care settings and dispensed in pharmacies (see Box 1). Despite the de-regulation of mifepristone at the federal level, a number of barriers persisted throughout the study period at the organizational and individual levels which made it difficult to implement in primary care. These barriers included provincial variation in patient subsidies and physician billing codes, provincial restrictions from the Quebec College of Physicians, and lack of motivation to provide mifepristone among some family physicians who assumed that abortion was already accessible in their communities. Ongoing implementation of mifepristone will require Canadian organizations to create tailored solutions to these local barriers, which may include creating new billing codes, provincial policy advocacy efforts in Quebec, and conducting physician engagement to raise awareness of access barriers. Reflecting the variation in regulations between provinces, perceptions of barriers were lower in British Columbia, Ontario, and Alberta, and highest in Quebec, where availability was further delayed. In spite of these barriers, participants held strong perceptions that mifepristone was the new standard of care for medical abortion in Canada and within the scope of primary care practice.

Interpretation

Our results are consistent with research in high-income nations, which documents that federal regulations are barriers to uptake of mifepristone.[12,29,30] Participants in our study who did not intend to engage in medical abortion expressed a sense of 'inertia' similar to those reported by Australian general practitioners, who perceived that abortion is a service provided in specialist clinics, and that abortion will draw unwanted stigma. Our results suggest providers may incorrectly perceive medical abortion risks to be greater than those related to continued pregnancy, despite strong evidence to the contrary.[1,32–34] Loss to follow-up may occur in 10-20% of medical abortion cases. However, international studies have demonstrated that severe complications are rare.[1,36]

Our research may have important implications for the U.S., where a number of the restrictions that Health Canada repealed are still mandated nationwide. The U.S. Risk Evaluation and Mitigation Strategy (REMS) for mifepristone includes elements to ensure safe use of the drug: 1) pharmacists cannot dispense directly to patients, 2) prescribers must be registered with the drug distributor, and 3) patients must sign a mandated "agreement" form.[14] Our results demonstrate that Canadian physicians perceived these elements would not enhance safety, would discourage other physicians from practice, and would limit access to abortion. The experience of implementing mifepristone in the absence of regulations will be relevant for jurisdictions like the U.S., and may be useful in efforts to bring the drug label in line with current international practice and evidence.[37,38]

Strengths and Limitations

Our results will have relevance for other high-income nations where medical abortion is provided in primary care settings. Canada's experience illustrates how evidence-based deregulation of mifepristone may facilitate its provision and increase access. Strengths of our study are our national sample, interviews conducted at two time points, and inclusion of new and experienced abortion providers, physicians not involved in abortion services, and stakeholders responsible for rural and urban family planning services. These stakeholders are ideally positioned to reflect on the factors that influence uptake of medical abortion at an individual, organizational, and system level. An additional strength of this national sample is our inclusion of experiences of practitioners from regions with historically limited abortion access, including the Territories and Atlantic provinces. Our results may be limited by including only one nurse practitioner in the sample, who became eligible to provide medical abortion during the study. In future research, our team will explore their perspectives, as well as those of midwives, patients, and pharmacists. We investigated mifepristone implementation in its early phase, during which Health Canada made significant changes to the regulation of this drug. As use and familiarity with mifepristone increase, the barriers and facilitators will likely change.

Conclusion

In the first two years since mifepristone has been made available in Canada, rapid regulatory revisions greatly assisted primary care practitioners to implement abortion care, particularly in rural communities. These changes have led to health care professional perceptions that there are minimal regulatory barriers to medical abortion practice. Our results are unique internationally as Canada is the first nation to facilitate provision of medical abortion in primary care settings through evidence-based deregulation of mifepristone.

Acknowledgements

Thank you to past and present members of the CART-Mife Implementation Study team for providing their expert and professional feedback in preparing this study: Stirling Bryan, Janusz Kaczorowski, Tamil Kendall, Eleni Stroulia, Flora Teng, Ashley Waddington, Glenys Webster. Our thanks to Marianne Manuge for translation of interviews from French to English. This study was supported by a Canadian Institutes of Health Research Partnership for Health System Improvement Grant (PHE148161), in partnership with the Michael Smith Foundation for Health Research (16743), and by a research grant from the Society of Family Planning (SFPRF11-19). SM was supported as a Trainee and a Scholar of the Michael Smith Foundation for Health Research (16603, 18270). WVN was supported as a Scholar of the Michael Smith Foundation for Health Research (2012-5139 (HSR)), and as an Applied Public Health Research Chair by the Canadian Institutes of Health Research (CPP-329455-107837). In kind support was contributed by the Society of Obstetricians and Gynaecologists of Canada (SOGC), the College of Family Physicians of Canada, the Canadian Pharmacists Association, and the Women's Health Research Institute of British Columbia Women's Hospital and Health Centre of the Provincial Health Services Authority of British Columbia. The SOGC supported development and design of the Community of Practice Platform that contributed to participant recruitment and retention through a contract with the last author's institution. All grants underwent external peer review for scientific quality and the funders played no role in conducting the research or writing the paper.

Conflicts of Interest

None declared.

References

1. Costescu D, Guilbert E, Bernardin J, et al. Medical Abortion. *J Obstet Gynaecol Can*. 2016;38(4):366-389. doi:10.1016/j.jogc.2016.01.002

2. Black A, Guilbert E, Co-Authors, et al. Canadian Contraception Consensus (Part 1 of 4). *J Obstet Gynaecol Can JOGC J Obstétrique Gynécologie Can JOGC*. 2015;37(10):936-942.

3. Norman WV. Induced abortion in Canada 1974-2005: trends over the first generation with legal access. *Contraception*. 2012;85(2):185-191. doi:10.1016/j.contraception.2011.06.009

4. Norman WV, Guilbert ER, Okpaleke C, et al. Abortion health services in Canada. *Can Fam Physician*. 2016;62(4):e209-e217.

5. United Nations Office of the High Commissioner on Human Rights. *Convention on the Elimination of All Forms of Discrimination against Women: Concluding Observations on the Combined Eighth and Ninth Periodic Reports of Canada.*; 2016:15. https://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=20708&LangID=E. Accessed June 11, 2019.

6. Sethna C, Doull M. Spatial disparities and travel to freestanding abortion clinics in Canada. *Womens Stud Int Forum*. 2013;38:52-62. doi:10.1016/j.wsif.2013.02.001

7. Sethna C, Doull M. Far from home? A pilot study tracking women's journeys to a Canadian abortion clinic. *J Obstet Gynaecol Can JOGC J Obstétrique Gynécologie Can JOGC*. 2007;29(8):640-647.

8. Dunn S, Cook R. Medical abortion in Canada: behind the times. *Can Med Assoc J*. 2014;186(1):13-14. doi:10.1503/cmaj.131320

9. Health Canada. *Regulatory Decision Summary: MIFEGYMISO*. Ottawa; 2015. http://www.hc-sc.gc.ca/.

10. Newton D, Bayly C, McNamee K, et al. '…a one stop shop in their own community': Medical abortion and the role of general practice. *Aust N Z J Obstet Gynaecol*. July 2016:n/a-n/a. doi:10.1111/ajo.12507

11. World Health Organization. *WHO Model List of Essential Medicine*.; 2017. http://www.who.int/medicines/publications/essentialmedicines/en/.

12. Jones RK, Henshaw SK. Mifepristone for early medical abortion: experiences in France, Great Britain and Sweden. *Perspect Sex Reprod Health*. 2002;34(3):154-161.

13. Templeton A, Grimes DA. Clinical practice. A request for abortion. *N Engl J Med*. 2011;365(23):2198-2204. doi:10.1056/NEJMcp1103639

14. Mifeprex REMS Study Group. Sixteen Years of Overregulation: Time to Unburden Mifeprex. *N Engl J Med*. 2017;376(8):790-794. doi:10.1056/NEJMsb1612526

15. Baird B. Medical abortion in Australia: a short history. *Reprod Health Matters*. 2015;23(46):169-176. doi:10.1016/j.rhm.2015.10.002

16. Norman WV, Soon JA. Requiring physicians to dispense mifepristone: an unnecessary limit on safety and access to medical abortion. *Can Med Assoc J*. October 2016:cmaj.160581. doi:10.1503/cmaj.160581

17. Norman W, Munro S, Brooks M, et al. Could implementation of mifepristone address Canada's urban-rural abortion access disparity: a mixed methods implementation study protocol. *BMJ Open*. 2019;9:e028443. doi:http://dx.doi.org/10.1136/bmjopen-2018-028443

18. Rogers EM. *Diffusion of Innovation*. 5th ed. New York, NY, US: Simon Schuster; 2003.

19. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. *Milbank Q*. 2004;82:581-629.

20. Cook JM, O'Donnell C, Dinnen S, Coyne JC, Ruzek JI, Schnurr PP. Measurement of a model of implementation for health care: toward a testable theory. *Implement Sci*. 2012;7(1):59. doi:10.1186/1748-5908-7-59

21. Canadian Institutes of Health Research. *Guide to Knowledge Translation Planning at CIHR: Integrated and End-of-Grant Approaches*. Canadian Institutes of Health Research; 2012.

22. Pinnock H, Barwick M, Carpenter CR, et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ*. 2017;356:i6795. doi:10.1136/bmj.i6795

23. Patton M. *Qualitative Research & Evaluation Methods*. 4th ed. London: Sage Publications (CA); 2015. https://us.sagepub.com/en-us/nam/qualitative-research-evaluation-methods/book232962. Accessed August 18, 2016.

24. Saunders B, Sim J, Kingstone T, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant*. September 2017:1-15. doi:10.1007/s11135-017-0574-8

25. Sandelowski M. Sample size in qualitative research. *Res Nurs Health*. 1995;18(2):179-183. doi:10.1002/nur.4770180211

26. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101. doi:10.1191/1478088706qp063oa

27. Health Canada. MIFEGYMISO (mifepristone and misoprostol tablets) - Updates to Product Monograph and Risk Management Plan. Healthy Canadians - Government of Canada. http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/65030a-eng.php. Published November 7, 2017. Accessed November 17, 2017.

28. Contraception and Abortion Research Team (CART-GRAC). Canadian Abortion Providers Support (CAPS CPCA). Community of Practice. https://www.caps-cpca.ubc.ca/index.php?title=Main_Page. Accessed June 12, 2019.

29. Yanow S. It Is Time to Integrate Abortion Into Primary Care. *Am J Public Health*. 2012;103(1):14-16. doi:10.2105/AJPH.2012.301119

30. Grossman D, Goldstone P. Mifepristone by prescription: a dream in the United States but reality in Australia. *Contraception*. 2015;92(3):186-189. doi:10.1016/j.contraception.2015.06.014

31. Dawson AJ, Nicolls R, Bateson D, et al. Medical termination of pregnancy in general practice in Australia: a descriptive-interpretive qualitative study. *Reprod Health*. 2017;14(1):39. doi:10.1186/s12978-017-0303-8

32. Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. *Obstet Gynecol*. 2012;119(2 Pt 1):215-219. doi:10.1097/AOG.0b013e31823fe923

33. Joseph KS, Liu S, Rouleau J, et al. Severe maternal morbidity in Canada, 2003 to 2007: surveillance using routine hospitalization data and ICD-10CA codes. *J Obstet Gynaecol Can*. 2010;32(9):837-846. doi:10.1016/S1701-2163(16)34655-2

34. Schummers L, Norman WV. Abortion services in Canada: access and safety. *CMAJ*. 2019;191(19):E517-E518. doi:10.1503/cmaj.190477

35. Warden S, Genkin I, Hum S, Dunn S. Outcomes during early implementation of mifepristone-buccal misoprostol abortions up to 63 days of gestation in a Canadian clinical setting. *J Obstet Gynaecol Can*. 2019;41(5):647-652. doi:10.1016/j.jogc.2018.05.030

36. Raymond EG, Shannon C, Weaver MA, Winikoff B. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. *Contraception*. 2013;87(1):26-37. doi:10.1016/j.contraception.2012.06.011

37. Gold M, Chong E. If we can do it for misoprostol, why not for mifepristone? The case for taking mifepristone out of the office in medical abortion. *Contraception*. 2015;92(3):194-196. doi:10.1016/j.contraception.2015.06.011

38. Foster AM, Jackson CB, LaRoche KJ, Simmonds K, Taylor D. From qualified physician to licensed health care professional: the time has come to change mifepristone's label. *Contraception*. 2015;92(3):200-202. doi:10.1016/j.contraception.2015.06.022

Table 1: Characteristics of participants

Characteristics	No. (n=90)
Profession	
Family Physician / General Practice	45
Gynaecologist	8
Other primary health care professional*	2
Stakeholder	
College or regulatory body	13
Advocate or advocacy group	9
Government	7
Abortion facility	6
Total	90
Region**	
National	9
British Columbia	19
Prairies (Alberta, Saskatchewan, Manitoba)	14
Ontario	14
Quebec	20
Atlantic (New Brunswick, Nova Scotia, Newfoundland)	9
Territories (Yukon, Northwest Territories, Nunavut)	5
Total	90
Gender (self-reported)	
Female	68

Male	20
Other/did not respond	2
Total	90
Health care professional age (n=55)	
20-29	5
30-39	25
40-49	11
50-59	10
60-69	4
Total	55
Health care professional practice location (n=55)	
Urban	33
Rural	22
Total	55
Health care professional abortion experience at time of study enrollment (n=55)	
Both	24
Surgical only	9
Medical only	5
None	17
Total	55

* Other primary health care professional (e.g. nurse practitioner, emergency medicine)

** Participants reported collectively from some provinces and territories to protect anonymity due to small numbers.

Box 1. Changes to Health Canada regulations for mifepristone-misoprostol medical abortion, as of January 2020

Topic	Change	Date changed
Observed ingestion	Removed requirement for observation of mifepristone ingestion. The patient can take the medication where and when they choose.	October 2016
Training	Removed requirement for training for pharmacists.	May 2017
Training	Removed requirement for training for prescribers.	November 2017
Consent form	Removed requirement for a manufacturer consent form to be signed by the patient.	November 2017
Registration	Removed requirement for registration of prescribers or pharmacists with the manufacturer.	November 2017
Dispensing	Mifepristone can be dispensed directly to patients by a pharmacist or prescribing health professional, rather than the original requirement that a physician must dispense directly to the patient.	November 2017
Gestational age	Mifepristone-misoprostol may be used up to nine weeks (63 days) from last menstrual period, rather than the original seven weeks (49 days).	November 2017

Ultrasound	Removed requirement for mandatory ultrasound prior to prescribing.	April 2019

Appendix 1: Interview Guides

Interview Guide A

Physician initial interview (3 months after training to prescribe mifepristone)

To begin, please tell me about your practice setting and your role in it.

1. Can you please tell me about your experience with mifepristone so far?
    a. *How many mifepristone terminations have you provided to date?*
    b. *How does that compare to the number of terminations you typically provide using other methods?*
2. What is your past experience with abortion care? (*Probe for type of abortion services available*)
3. What do you feel are the advantages of mifepristone as a new treatment?
    a. *Do you see there being any downsides to having mifepristone available in Canada?*
4. How do other providers in your community feel about mifepristone and abortion care?
    a. *What are your relationships like with other key people in your community? (Such as other providers, pharmacists, managers)*
    b. *Do/Did you have a formal plan for implementing mifepristone in your community? What does it look like?*
    c. *Can you describe the patient care pathway for mifepristone medical abortion in your practice? (Such as appointments, prescribing, dispensing, and where and how each step takes place)*

I would like to talk a little more about any obstacles you have faced in providing mifepristone.

5. What things make it challenging to provide? Has _____ been a factor? (How?)
    - *Cost (such as provincial coverage, financial disincentives, uncertainty about coverage)*
    - *Billing codes (such as lack of billing codes; lack of compensation)*
    - *Clinical workflow (such as counselling; following up; changing from a surgical to a medical abortion clinic; time pressure)*
    - *Documentation (such as Health Canada forms, consent forms)*
    - *Drug availability and dispensing (such as ordering it)*
    - *Government support (such as political factors)*
    - *Regulations (such as physician dispensing)*
    - *Community presence of anti-choice attitudes (such as among protestors or colleagues)*
    - *Having access to surgery, ultrasound, or labs*
    - *Human resources (such as counsellors; staff burn out)*
    - *Availability of information (such as confusion about regulations; where to get training; where to get updates)*
    - *Training (such as the requirement to get training)*

6. What changes would make it easier for you to provide mifepristone?

Let's talk about your experience with the training program:

7. What made you decide to take the mifepristone training program?
8. What was your experience of the training process?
    a. *How easy or difficult was it to get the training?*
    b. *Was this a typical training experience for you? How was it different from how you*

typically do professional development?

c. *How could the training be improved?*

I would also like to know about any support or feedback you are receiving. We spoke earlier about your relationships with your colleagues in your community.

9. Are there any key individuals that have rallied to support mifepristone, either in your community or elsewhere in Canada? Can you describe what they did?
    a. *Is there any person or organization you would describe as unsupportive? (What did they do?)*
10. Have you exchanged information with anyone about mifepristone, either inside or outside of your setting?
    a. *What did that look like? (For instance, have you spoken to the media or contacted your college registrar?)*
    b. *Have you learned about any changes to mifepristone regulations or coverage? What have you learned? Where did you get the information?*
11. Are you a member of the Canadian Abortion Providers Support platform, also known as the "CAPS" website?
    a. If YES: *Tell me your thoughts about it. / What do you like or dislike about the website? / How can it be improved?*
    b. If NO, explain what the website is before following up: *Would joining this website be useful for you? (Why / why not?) / To help us make it useful for you, what information would you want from the website?*
12. What do you like about other communities of practice that you belong to, such as email list serves?
13. How will you know that you are achieving good outcomes with mifepristone in your community?

I have come to the end of my questions.

14. Is there anything else you think I should know?
15. Do you have any questions for me?

Interview Guide B

Healthcare professionals, such as family physicians, who were eligible to become mifepristone prescribers but did not pursue this practice

1. Please tell me about your practice setting and your role in the past 12 months.
    a. *What are the areas of focus for your clinical practice?*
2. Can you please tell me what you know about medical abortion and the new abortion pill called mifepristone?
3. What do you feel are the advantages of the new abortion pill?
    a. *Do you see there being any downsides to having the abortion pill available in Canada?*
4. Have you ever provided abortion care before? Can you please describe the care you provided?
    a. *How do you feel about abortion?*
5. Are you aware of the Society of Obstetricians and Gynaecologists of Canada mifepristone training program for physicians and pharmacists?
    a. If YES: *Tell me your thoughts about it.*
    b. If NO, explain what the training is before following up: *Would taking this training be useful for you? (Why / why not?)*
6. Can you describe the abortion care available in your practice setting or community?
7. How do other providers in your community feel about the abortion pill?
    a. *What are your relationships like with other key people in your community who would be involved in providing the abortion pill? (Such as other physicians, pharmacists, managers)*
    b. *What are your relationships like with abortion providers?*
    c. *What relationships or networks do you feel are necessary for you to provide the abortion pill?*
    d. *Do you have a formal plan for implementing the abortion pill in your community? Do you know of anyone else's plans? What does they look like?*
8. Are there any key individuals that have been leaders in implementing the abortion pill, either in your community or elsewhere in Canada? Can you describe what they did?
    a. *Is there any person or organization you would describe as unsupportive? (What did they do?)*
9. Have you exchanged information with anyone about the abortion pill, either inside or outside of your setting?
    a. *What did that look like? (For instance, have you spoken to the media or contacted your college registrar?)*
    b. *Have you learned about any changes to abortion pill regulations or coverage? What have you learned? Where did you get the information?*

I would like to talk a little more about any factors that may be an obstacle for you to providing the abortion pill.

10. Has _____ been a factor? *(How?)*
    - *Cost (such as provincial coverage, financial disincentives, uncertainty about coverage)*
    - *Billing codes (such as lack of billing codes; lack of compensation)*
    - *Clinical workflow (such as counselling; following up; changing from a surgical to a medical abortion clinic; time pressure)*
    - *Documentation (such as Health Canada forms, consent forms)*
    - *Drug availability and dispensing (such as ordering it)*

- *Government support (such as political factors)*
- *Regulations (such as physician dispensing)*
- *Community presence of anti-choice attitudes (such as among protestors or colleagues)*
- *Having access to surgery, ultrasound, or labs*
- *Human resources (such as counsellors; staff burn out)*
- *Availability of information (such as confusion about regulations; where to get training; where to get updates)*
- *Training (such as the requirement to get training)*

11. Would you ever consider providing medical abortion with mifepristone?
    a. If YES*: What changes would make it easier for you to provide?*
        i. *Probe for changes to their personal opinions; professional support; training; policies and regulations; practical aspects of practice*
    a. If NO*: Why?*

12. What support or feedback would be necessary for you to practice mifepristone medical abortion?
13. Are you aware of the Canadian Abortion Providers Support platform, also known as the "CAPS" website?
    a. If YES: *Tell me your thoughts about it.*
    b. If NO, explain what the website is before following up: *Would joining this website be useful for you? (Why / why not?) / To help us make it useful for you, what information would you want from the website?*
14. How will you know that the abortion pill is well received and used in your province?

I have come to the end of my questions.

15. Is there anything else you think I should know?
16. Do you have any questions for me?
17. Is there anyone else you recommend we talk to?

Interview Guide C

Physician repeat interview (12 months after initial interview)

1. Please tell me about your experience since our interview on [Month/Date].
   a. Have you begun to <u>prescribe</u> mifepristone? Why / Why not?
   b. Have others in your community begun to prescribe mifepristone?

If they provide mifepristone:

2. Can you describe the patient care pathway for mifepristone medical abortion in your practice? (*Such as appointments, prescribing, dispensing, and where and how each step takes place*)

I would like to talk a little more about any obstacles you have faced in providing mifepristone.

3. In our last interview, you said that these things have been a factor for you in providing mifepristone: [*list factors*] I'm going to go through each of these one at a time.
4. Is _____ still a factor for you? (*How? What has changed? Why?*)
   a. [Probe about new factors that emerged from data collection and analysis after the participant's interview]
5. Are there any other changes that would make it easier for you to provide mifepristone?

I would also like to know about any support or feedback you are receiving.

6. Since our last interview, have you exchanged information with anyone about mifepristone, either inside or outside of your community?
7. Have you learned about any changes to mifepristone regulations or coverage? What have you learned? Where did you get the information?
8. Are you a member of the Canadian Abortion Providers Support platform, also known as the "CAPS" website?
   a. If YES: *Tell me your thoughts about it. / What do you like or dislike about the website? / How can it be improved?*
   b. If NO: *Why did you choose not to join the CAPS website?*

I have come to the end of my questions.

9. Is there anything else you think I should know?
10. Do you have any questions for me?

Interview Guide D

Stakeholders

1. Please tell me about your role and your organization.
2. How long have you been in this role?
3. From your perspective, please tell me the story of how mifepristone came to be in Canada.
4. When did you first get involved with bringing mifepristone to Canada? What has your role been?
5. Tell me about your understanding of the rules and regulations set by Health Canada.
6. Tell me about your understanding of the rules and regulations set by your regulatory body.
7. Tell me your process for implementing mifepristone in your organization/setting.
8. How have those processes changed since approval?
9. What would you have done differently?
10. What have the challenges been? *Probe for the following and for factors that emerge from data collection/analysis with physicians:*
    - *Cost / Financial disincentives / Coverage*
    - *Pharmacy stock*
    - *Access to surgery, ultrasound, labs*
    - *Government support*
    - *Regulations (product monograph, Risk Management Plan, training)*
    - *Human resources (i.e. turnover, burnout)*
11. What has reduced those challenges?
12. What needs to change to make it easier to implement mifepristone in your setting?
13. Who are the different groups involved in implementing mifepristone? What have they done?
14. Tell me about how you have engaged with other groups? *Probe for the following:*
    - *Key individual, experts*
    - *Degree of support (or unsupportive)*
    - *Degree of communication*
    - *Quality of information exchange*
    - *Feedback with the media*
15. Can you tell me about your organization's values and how they relate to mifepristone?
16. What are the advantages of mifepristone as a new treatment?
17. Can you describe any potential downsides to implementing mifepristone?
18. How will you know that you are achieving good outcomes with implementing mifepristone?
    a. What kind of outcomes are you tracking or looking for or look for? \
    b. How do you measure successful implementation of Mife?
19. Is there anyone else you recommend I speak with?
20. Is there anything else you think I should know?
21. Do you have any questions for me?

Appendix 2: Themes and Representative Quotations

Table 1: Federal restrictions made mifepristone "more complicated than it needs to be"
Physicians' ability to implement mifepristone in routine care was influenced by federal restrictions

Theme	Description	F	B	Quotation
Mandated training and certification	Prescribers and dispensers were required to complete a training program		X	"It [the training] is going to limit women's access to medications. It might be a person, for example -- I've seen this – where they're intent to do this module, but they just haven't gotten around to it. Then suddenly you have a patient there who wants a medical, and they just don't have the time to do it, to go through the module and get the prescribing right. That's a barrier versus if you could prescribe the medication and then get some mentorship by someone who has experience with using the medication, which is kind of how we use all of our medications." *006_Phys – family physician from the Territories, previous medical and surgical abortion experience*
	Prescribers and dispensers were required to certify their identity with the manufacturer		X	"Until recently, we had to get registered with the company as [abortion] prescribers, and I really was uncomfortable with that. We did it, but I really hated the notion that a private corporation has my name, address, and information. If they get hacked, that information could be potentially accessed, if there was a data breach." *035_Phys – primary care professional from the Territories, previous medical and surgical abortion experience*
Limits on prescribing and dispensing	Physician-only dispensing		X	"We're not set up to dispense medications from our office. We wouldn't have been able to dispense it just through the clinic that I work in. I think, that's better, that it's not dispensed by physicians. I don't know of any other medication that is dispensed by physicians." *036_Phys – rural Saskatchewan family physician, previous medical and surgical abortion experience*
	Prescribers were required to provide 24 hour on-call follow up for patients		X	"The sort of requirement to be available on call is no fun because that is not traditionally how I practice. I've basically gotten a second phone just to use for on call, which is a nuisance. I don't want to give my private cell number, but I don't have a call service. Traditionally I don't have to do after hours … it bugs me that we're expected to be on call for free, forever" *029_Phys – rural British Columbia family physician, no previous abortion experience*
Restrictions for patient access	Mandated patient consent form		X	"I know we had groups to talk to us that said, 'This is ridiculous. Women shouldn't be walking around with their informed consent and giving that to the pharmacy to the prescription filled.' We said, 'What are you talking about?' There was information out there that it was a requirement from Health Canada, which was not the case. When we heard that that was an option to have women carry their informed consent and show that at

			the pharmacy, we didn't think that was a good idea. We actually rejected that. We said, 'We don't think for various privacy concerns that that's appropriate.'" *007_Stakeholder – government decision maker*
	Requirement to watch the patient ingest the drug	X	"I've never seen any other drug – and we've prescribed lots of toxic, horrible things – that had to be given by the doctor directly and watch the patient take the dose." *008_Phys – rural Saskatchewan family physician, no previous abortion experience* "It was interpreted to mean that the patient would have to be in the presence of a doctor, in front of the doctor to take the drug, which was kind of unheard of for any drug to be handled that way. It was perceived as being very paternalistic; 'Women can't be trusted.'" *022_Stakeholder – national advocate*
	Gestational age limit was lower than recommended by guidelines	X	"I mean, the Health Canada original guideline really conflicted with the SOGC guideline in what the evidence stated. … There is strong evidence that Mife is good up to nine, 10 weeks. I think that that is something that I would be willing to do and other providers at our facility would too." *015_Phys – urban Saskatchewan family physician, previous medical and surgical abortion experience*
	Ultrasound to confirm gestational age required before prescription	X	"Right now, an ultrasound is required. Maybe that can soften too. If this woman has regular periods at exactly every 28 or 30 days or whatever their period is, they had a normal, regular period, and now they are pregnant and now are starting to get sore breasts. If you are in a remote community where ultrasound is not accessible, maybe you can actually trust women." *020_Phys – urban Ontario family physician, previous surgical abortion experience*
Perceptions of the policy process	Regulatory approval of mifepristone in Canada was "slow"	X	"I was thrilled that it was going to be approved. I felt like it was a long time coming." *030_Phys – urban Ontario family physician, previous surgical abortion experience* "It just seemed like Health Canada was a little bit slow. Kind of like mifepristone was regulated in a way that almost no other drug that I use as a family physician is regulated, right?" *015_Phys – urban Saskatchewan family physician, previous medical and surgical abortion experience*
	Federal politics and policies influenced the approval process	X	"The original application was initiated during the Conservative government, so they [the distributor] were probably strategically positioning that application in a way that would have been a bit more palatable for acceptance, or they were hoping would not have the resistance, but now that we have a supportive federal government in place and don't expect that kind of resistance and certainly have been working hard with Health Canada, etc., you know. There's some back work to do now to kind of remove some of the initial

	strategies and approaches." *008_Stakeholder – government decision maker*

F: Facilitator; B: Barrier

Table 2: Navigating the "huge bureaucratic process" of organizational implementation
Physicians' ability to implement mifepristone in routine care was influenced by health system and structural factors

Theme	Description	F	B	Quotation
Billing and costs	Physician compensation for medical abortion	X	X	"I don't even have a billing code for telemedicine. I don't have a billing code for medical abortions. I don't have a billing code for ultrasounds out-of-hospital. I don't have a billing code for any of the counselling that we do … Suggesting that introducing Mife is just all of a sudden going to increase regional access to abortion, I think, is egotistical of people." *005_Phys – urban New Brunswick family physician, previous medical and surgical abortion experience*
	Patient affordability and provincial coverage	X	X	"I think the biggest thing is cost. That's the hugest thing. To offer women, 'Here you can have a medication abortion or a surgical procedure' and say, 'The surgical procedure is free, but you have to pay $325' — or whatever it is — 'for your medication abortion,' I think that's not giving a, it's not a real choice. I think that's a problem." *001_Phys – rural British Columbia family physician, previous medical and surgical abortion experience*
Bureaucracy	Local administrative and procedural obstacles		X	"We're part of a hospital. There's a huge bureaucratic process that I have had very little to do with implementing. I'm just going to just wait and apply with it when it becomes [available] … Once we do, it'll just be part of routine care." *003_Phys – urban Ontario family physician, previous medical and surgical abortion experience* "I would love to be able to [prescribe]. That's not in my realm of decision making ... I've asked at our meeting what could potentially be happening. I asked that kind of directly to the [Department Head], and they kind of said they really haven't heard anything yet and more information should be maybe forthcoming, so that's the last I've heard from them. I plan to bring it up again in our next meeting" *025_Phys – rural Nova Scotia family physician, no previous abortion experience*
	Moving ahead in some provinces, while lagging behind in others	X		"The College of Physicians and Surgeons and College of Pharmacists in Ontario and BC have basically come out with statements telling their members that you can, basically, ignore the Health Canada requirements. You don't have to do an ultrasound unless you think it is necessary … pharmacists can now dispense directly to patients. We have gotten rid of that requirement or that expectation, at least, in those two provinces." *022_Stakeholder – national advocate* "Well, firstly, I think the big mistake was wanting to bring in the Mife abortion pill to Quebec, as it was done in the rest of Canada. Secondly, Quebec is not only different in terms of the number of abortion services, but also in terms of its laws. So, Health Canada does not have

			all the powers, even in Quebec. The Collège des médecins is the other party that one must work with to develop this type of thing." *Stakeholder E4 – facility leader*
Rural care	Population and resource needs of rural communities	X	"Yesterday, I did a surgical termination on a woman who had to travel literally 12 hours from the northern part of the province for a surgical procedure. I kept thinking, you know, if there had been a provider in her community or a nurse practitioner who could have done a medical. She had to leave four children in a community that's 12 hours away, right?" *002_Phys – rural British Columbia OB-GYN, previous medical and surgical abortion experience*
Implementation process	Access to ultrasound, laboratory, and surgical resources	X	"There is the assumption that you have speedy laboratory and access to ultrasound. That just isn't always the case because when we do have an ultrasound tech, it's usually a long list. Doing a dating ultrasound is pretty low priority for most of the things that are out there." *026_Phys – rural family physician from the Territories, previous medical and surgical abortion experience* "My experience with medical abortions done with methotrexate and misoprostol is it's something you want to make sure is covered but not because you ever need it, but because you might need it. So access to urgent D&C, for instance, if need be, would be important, but the truth is with any place where they're going to have miscarriages, which is everywhere, would also have to have access to those services, so it's no more of an issue for this than it is for a miscarriage." *016_Stakeholder – College/regulatory body decision maker*
	Finding ways to stock and dispense the drug	X	"Initially, it seemed to be that I would have to order them, pay, and charge the patient, and they may or may not get it reimbursed from the insurance. I think if I had to go through that process, that would be difficult in sorting out, 'How am I going to be stocking this in my office? How am I going to charge patients?' From my understanding, that has been eased, and I can actually just prescribe it." *004_Phys – urban Ontario family physician, no previous abortion experience*
	Getting experience with the tasks of a new practice	X	"I've prescribed it, I think, only once … I had the perfect patient come into my office who I knew would be a candidate, so we scrambled to get the investigations done. I spent a summer weekend doing the online training and then prescribed it. The pharmacy was really open to doing it. They were like, 'Yeah, we were meaning to ask you if we should do this.' I was like, 'I've been meaning to ask you guys if we should do this,' so we did, and it was textbook. She was the perfect candidate. It went perfectly. No problems. No hitches, and it was great." *034_Phys – rural Nova Scotia family physician, no previous abortion experience*

	Task shifting from a surgical to medical abortion practice	X	X	"We were so surgically focused, when we got around to dedicating a whole day to doing medical abortions because the demand was that high, we didn't really lay off staff because we have so many casual people. We had to reorganize our day so that instead of having five nurses on, we only needed one. That was a bit of a change for the clinic. Moving forward, if we have to do more of that, then that will be a significant change for this site because we have been organized as a surgical facility, and we will end up being more like a doctor's office." *003_Stakeholder – abortion facility administrator*
	Patient counselling	X		"We're not trained counsellors, and we are often pressed for time. Again, in our dream world, we would have a counsellor on site as well, so the woman could see us and also a counsellor." *031_Phys – family physician from the Territories, previous medical and surgical abortion experience*
	Patient follow-up		X	"We have many patients that come from different cities, up to an hour, an hour and a half away. We would love to do some of the follow-up just over the phone, so they physically don't have to come in, but we do not have a way of getting the blood work in other facilities. The only way we can do it is have them physically come to the hospital to have that done. That was another obstacle." *028_Phys – urban Ontario family physician, previous medical and surgical abortion experience*

F: Facilitator; B: Barrier

Table. 3: Challenges with diffusion and dissemination of policy information
Physicians' ability to implement mifepristone in routine care was influenced by communication and interaction with colleagues, advocacy groups, and news media

Theme	Description	F	B	Quotation
Collegiality	Collaboration with peers, consultants, and pharmacists to make implementation work	X		"We do a lot of just 'off the side of our desk' medicine in a rural setting, so when you do something for the first or second time or you don't do it very often, it's good to have other medical colleagues you can run something by or say, 'What do you think of this? Is this crazy? Do you have any other ideas?' That is huge for me when I'm trying something new or doing something new just to have others around me that maybe don't have a lot more experience than me but that are supportive and a good sounding board." *040_Phys – rural British Columbia family physician, previous medical abortion experience*
	Having a mentor	X		"We just had an e-mail come round through the Division of Family Practice from the obstetrician in [city] who does the unplanned pregnancy clinic saying she sees these women coming to her from here, and she knows it's difficult, and can she support us in getting started [with mifepristone], and do we want a session? I replied, 'Yes, I absolutely would love that.' That would actually be the thing that would nudge me over the edge I think would just be to have that personal contact." *039_Phys – rural British Columbia family physician, no previous abortion experience*
Communication	Making sense of changing and inconsistent information on regulations		X	"I think it's good for people to wait a little bit and not kind of jump in because it gets confusing … I kind of want to wait until some other changes happen so I can say, 'This is how it is. You don't need pharmacists to do this. Physicians aren't required to do this,' or whatever because to *undo* information will be a lot harder." *008_Stakeholder – government decision maker*
	Availability of a community of practice for quality information	X		"I think it [the Canadian Abortion Providers Support (CAPS) platform] is a fantastic resource because it has a lot of information on how to provide services, on where to find pharmacists. I like the fact that it is a sort of members only website, at least some parts of it. I think there's been a lot of design going into making that a safe and non-hackable space … It's sort of a nice centralized way of getting information and distributing information to the people who are among the providers." *021_Phys – urban British Columbia OB-GYN, previous medical and surgical abortion experience*
	Awareness of mifepristone as a new option		X	"I don't think patients know about it, but it's even more important for doctors. I don't think doctors know about it, ones who aren't watching for it. For me, it was on my radar because it was interesting to me. It was an equity issue for me, but I am not, like,

			your average person. I have a particular interest in it, right?" *008_Phys – rural Saskatchewan family physician, no previous abortion experience* "I did speak to the owner of the pharmacy that we deal with all the time about it being on the market. She didn't even know what it was. When I was saying, 'Mifegymiso is now available.' She said, 'What is that?' I said, 'It is the abortion pill.' She was like, 'I had never heard of it.'" *020_Stakeholder – Atlantic province abortion facility administrator*
Being an advocate	The role of advocacy in improving access to family planning services	X	"I think what people don't understand is if a woman wants to terminate a pregnancy, she will. That means that she will even do it illegally or dangerously, and she will terminate that pregnancy. What we are going to see if there are any cutbacks on abortion services, we are going to see injured and sick and even dead women. That's why I feel that I am more resolved to provide those services." *033_Phys – urban Ontario OB-GYN, no previous abortion experience*
Anti-choice attitudes	Avoiding scrutiny as an "abortion doctor"	X	"Some of them that are abortion providers basically have to sneak their way into the clinic so people picketing outside don't see them or they don't let their extended family know that they are abortion providers. You certainly know that people that are living their life doing this don't feel like they can do it openly, which is unfortunate if you look at the support that there actually is amongst Canadians, that we still have to be doing it kind of in the dark." *004_Phys – urban Ontario family physician, no previous abortion experience*
	Experiencing conscientious objection	X	"The reason we don't do abortions at our hospital is essentially because of the insurmountable anti-choice elements among the staff. We would have cleaning people who wouldn't clean the OR. We would have nurses who wouldn't participate in the case. We would have a number of anaesthetists who wouldn't provide any kind of anaesthesia backup for the OBs who were doing abortions before at our hospital … We can't even start talking about Mife until we start talking about just accepting abortion as a whole." *005_Phys – urban New Brunswick family physician, previous medical and surgical abortion experience*

F: Facilitator; B: Barrier

Table 4: Adoption by individuals: 'A process rather than an event'
Physicians' ability, motivation, and skills to implement mifepristone in routine care

Theme	Description	F	B	Quotation
Perceived benefits of mifepristone	Mifepristone abortion is effective, reliable, and safe	X		"It's way more predictable than methotrexate and misoprostol. It's been much easier to use in my very limited experience, but even just talking to other people who have been using it, it's been much easier to use. I think there's going to be much more uptake from physicians who weren't normally providing abortions before but who will be open to do it because of the relative ease of using the mifepristone" *006_Phys – family physician from the Territories, previous medical and surgical abortion experience*
	Patients experience more comfort, options, and access with mifepristone	X		"I think there's huge benefits for the patient's convenience. I think in terms of being able to manage this in a primary care environment, including their home at their convenience, not when a surgeon is available or not. I think the patient has a lot control over the situation, so I see it as a huge benefit." *019_Stakeholder – Advocate*
Motivation	Experiencing motivation to start providing	X		"I had intentions of doing it [the training] … but then I had a referral with a patient requesting it, so that prompted me to get the certification done so that I would be able to do my best to provide that for her." *032_Phys – rural Saskatchewan OB-GYN, previous surgical abortion experience*
	Experiencing "inertia" (waiting to start providing)		X	"Knowing that there's all these fast-changing regulations, especially knowing that the pharmacy-training piece was going to fall away eventually is part of why I waited … I'm more hopeful now that I will be able to convince the pharmacists in the community to stock it." *021_Phys – urban British Columbia OB-GYN, previous medical and surgical abortion experience*
	Assuming there is good access and the service is not needed		X	"The availability is there. It's kind of mainly my own inertia … I feel like it's such a low barrier, but to be honest with you, it's an even lower barrier that I have my patients be seen by [an abortion clinic] across the street." *042_Phys – urban British Columbia family physician, previous medical abortion experience*
Experience	Gaining comfort and competence through hands-on experience	X		"We were very nervous to do medicals on people who were out in rural without much support, but we've moved increasingly to … being a lot less nervous about that. With Mife, our results are going to better, quicker, and more assured. That's going to be even less a constraint. [What caused that shift that made you less nervous?] I think experience." *018_Phys – urban Saskatchewan family physician, previous medical and surgical abortion experience*
Reinforcement	Observing patient satisfaction and drug effectiveness	X		"I see the same patients all the time. That patient, I've seen her three times since. She hugs me every time. She's so happy. That's a thing. You see, I would see them again and again and again because it's a small, defined community, so I will know. If somebody doesn't have a

	good outcome, I will know about that, too. In that way, it's very easy." *034_Phys – rural Nova Scotia family physician, no previous abortion experience*

F: Facilitator; B: Barrier