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Could implementation of mifepristone address Canada's urban–rural abortion access disparity: a mixed-methods implementation study protocol

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ABSTRACT

Introduction In January 2017, mifepristone-induced medical abortion was made available in Canada. In this study, we will seek to (1) understand facilitators and barriers to the implementation of mifepristone across Canada, (2) assess the impact of a 'community of practice' clinical and health service support platform and (3) engage in and assess the impact of integrated knowledge translation (iKT) activities aimed to improve health policy, systems and service delivery issues to enhance patient access to mifepristone.

Methods and analysis This prospective mixed-methods implementation study will involve a national sample of physicians and pharmacists recruited via an online training programme, professional networks and a purpose-built community of practice website. Surveys that explore constructs related to diffusion of innovation and Godin's behaviour change frameworks will be conducted at baseline and at 6 months, and qualitative data will be collected from electronic interactions on the website. Survey participants and a purposeful sample of decision-makers will be invited to participate in in-depth interviews. Descriptive analyses will be conducted for quantitative data. Thematic analysis guided by the theoretical frameworks will guide interpretation of qualitative data. We will conduct and assess iKT activities involving Canada's leading health system and health professional leaders, including evidence briefs, Geographical Information System (GIS)maps, face-to-face meetings and regular electronic exchanges. Findings will contribute to understanding the mechanisms of iKT relationships and activities that have a meaningful effect on uptake of evidence into policy and practice.

Ethics and dissemination Ethical approval was received from the University of British Columbia Children's and Women's Hospital Ethics Review Board (H16-01006). Full publication of the work will be sought in an international peer-reviewed journal. Findings will be disseminated to research participants through newsletters and media interviews, and to policy-makers through invited evidence briefs and face-to-face presentations.

Strengths and limitations of this study

► The mixed-methods design of this study will provide qualitative evidence to enrich the quantitative results and corroborate knowledge about the effect of health policy, system and service determinants on access to medical abortion.

► The potential of our research to make an impact on policy and practice is strengthened by an integrated knowledge translation approach (iKT), where decision-makers and practitioners are actively involved in collecting, analysing and interpreting our study data.

► Evaluation of our iKT approach of having decision-makers on the research team will contribute critical knowledge on which strategies are most effective at facilitating coproduced knowledge, mitigating barriers and improving equitable access to abortion.

with nearly one in three Canadian women having at least one abortion during their reproductive years.[1–3] However, access to abortion is not equitable. In 2012, 96% of Canadian abortions were performed using surgery, through fewer than 100 facilities, located primarily in Canada's largest cities within 150 km of the US border.[3 4] Historically in Canada, abortion provision has been included within the scope of practice only for physicians, and in 2012, it was offered by fewer than 300 doctors.[3 5] Under these conditions, patients living outside of major cities had to travel inordinate distances to reach service locations, experienced significant wait times and faced numerous barriers to equitable access to abortion service.[6 7] Notably, The United Nations Human Rights Commissioner's November 2016 Report of the Committee on Elimination of Discrimination Against Women expressed concern over inequitable abortion access in Canada and called

INTRODUCTION

Induced abortion is a common, safe and legal reproductive health procedure in Canada,

on the government of Canada to demonstrate improvement.[8] Canada's federal drug regulator, Health Canada, approved mifepristone, the gold standard for medical abortion,[5] in July of 2015.[9] Subsequently, mifepristone first became available to Canadians on 10 January 2017.[10]

Mifepristone was first introduced to the global marketplace in 1988. In other nations, the drug has not been associated with an increase in overall abortion rates, while it has increased the proportion of medical abortion compared with surgical.[11] Widely differing rates of mifepristone implementation, particularly in primary care settings, have been noted worldwide among countries with approval.[11–16] Uptake in the USA was among the slowest: at 10 years after approval, only 10% of all abortions were provided by mifepristone, compared with 70% in Scotland and 80% in Northern Europe.[11 13 14 16] Variation in health systems, provider training, provider support, drug regulations and legislated restrictions may account for these differences. Canada's geographical disparities in access to abortion care, particularly among rural and remote populations, call for innovative approaches to the implementation of mifepristone services, including strategies to support primary care providers to initiate and sustain abortion services. Mifepristone implementation has the potential to address current abortion service disparities and health access inequities, particularly among disadvantaged populations.

When mifepristone was approved in Canada, Health Canada specified several unique restrictions that could act as significant barriers to access. Namely, only physicians may prescribe and dispense mifepristone, and that those who provide mifepristone must be certified through an accredited online training programme.[9 17] Our multidisciplinary research team theorises that mifepristone training and practice could be undertaken by a range of healthcare professionals who are interested in providing mifepristone, including family physicians, nurse practitioners and midwives. Further, we postulate that, based on the above-cited evidence from international settings, mandatory training and certification without additional practice support will be insufficient to facilitate adoption and distribution of this innovation in the face of the federal restrictions, particularly among primary healthcare professionals in rural areas and/or without prior experience providing abortion. We further hypothesise that the identification and mitigation of implementation barriers and facilitators at the health policy, system and service delivery levels, particularly those affecting primary care providers, could advance mifepristone practice in Canada and improve equitable abortion care access.

Our study is informed by principles of integrated knowledge translation (iKT)[18] and Roger's Theory of the Diffusion of Innovation[19] in seeking to answer the question: 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 services access throughout Canada?
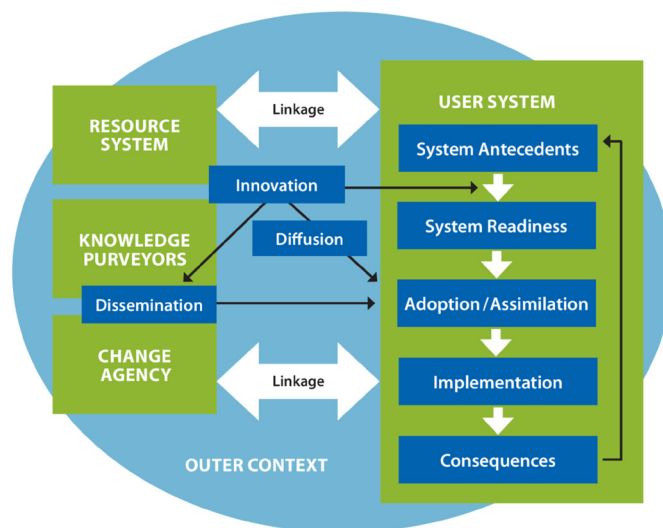

Figure 1 Determinants of diffusion of innovations in health service delivery organisations, adapted from Greenhalgh *et al*.[19]

METHODS
Aims
The aims of this study are:
► To understand health policy, system and service facilitators and barriers to the distribution and implementation of mifepristone abortion practice in primary care.
► To assess the impact of a 'community of practice' platform to detect and support clinical, health service and system challenges faced by clinicians adopting mifepristone medical abortion practice.
► To evaluate continuous iKT with and by health policy, health system, and health services decision-makers and health professional organisations to reduce barriers and optimise facilitators, for mifepristone abortion practice.

This study protocol is guided by the Standards for Reporting Implementation Studies statement.[20]

Conceptual frameworks
Our study uses a theoretical framework combining two theories to explain adoption and diffusion of innovations: Roger's Theory of the Diffusion of Innovation and Godin's framework. Greenhalgh *et al*[19] developed constructs to capture determinants for implementation, as articulated by Rogers' Theory of the Diffusion of Innovation,[21] in health service delivery and health systems (see figure 1). This comprehensive theoretical model of dissemination and implementation of health service innovations aims to support research for bridging the gap between knowledge and practice/policy. The model was developed from a systematic meta-narrative review of scientific evidence on factors related to implementation.[19] It articulates key constructs for capturing the complex processes of implementation: characteristics of the innovation and adopter; methods of diffusion and dissemination (eg, communication and influence); system antecedents and readiness; outer context; resource systems and change

agents; and their role in facilitating the implementation process.[19] Cook *et al* operationalised these constructs into semistructured survey and interview questions to allow researchers to generate evidence on barriers and enablers to implementation.[22]

Within these constructs, we further explore provider uptake and behaviours using Godin *et al*'s framework,[23] integrating the theory of planned behaviour[24] and Triandis' theory,[25] to predict intention and uptake of clinical behaviour. The strongest predictors of behaviour are intention, belief about capabilities, and frequency of past behaviour. Intention is influenced by belief about consequences, role identity, moral norm, social influences and personal characteristics. This framework has good application to practise in the abortion context, where role identity, moral norm and social factors could have strong influence on behaviour.[26]

Design

We designed a prospective mixed-methods observational research study on factors that influence implementation of mifepristone in primary care over the initial 2 years of practice in Canada. We hypothesised that healthcare professionals interested in adopting mifepristone care into their practice would have widely varied professional characteristics, practice locations and settings, and local or health system supports, and would serve a wide variety of disadvantaged and vulnerable populations; all of which may influence implementation and access to care. Our national, interprofessional research team (nursing, medicine, pharmacy, epidemiology, implementation science, medical sociology, computer science, public health and education) is composed of senior, mid and early career investigators, national and provincial policy-makers, healthcare and health professional organisations, clinicians, citizen groups and trainees. Our design is flexible and will be adapted in response to health system and policy changes. This will allow us to collect data in the setting, samples and contexts that may provide the richest information to answer our research questions.

Health system intervention

Mifepristone is marketed, in combination with misoprostol in Canada, as Mifegymiso, for the indication of early medical abortion (one mifepristone 200 mg tablet and four misoprostol 200 μg tablets). Mifepristone is used in more than 60 countries worldwide, is on the WHO list of essential medicines,[27] and has an excellent safety and effectiveness profile as illustrated by administration to millions of women.[28–30]

Mifepristone provided in primary care settings is an innovative health service delivery model for medical abortion. Until now, high-income country drug regulators have placed a range of unique restrictions on the distribution and administration of mifepristone,[31 32] which has largely limited provision of mifepristone to abortion providers in existing urban sexual and reproductive-specific health facilities that generally provide a high volume of surgical

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Box 1 Canadian restrictions for prescribing and dispensing mifepristone, July 2015

- ► Mandatory training for prescribers and pharmacists.
- ► Mandatory registration of prescribers and pharmacists with the manufacturer.
- ► Physician-only prescribing.
- ► Physician-only dispensing direct to the patient.
- ► Mandatory use of a manufacturer-provided consent form to be signed by the patient.
- ► Physician's observation of mifepristone ingestion.

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abortion services. In Australia, for instance, mifepristone by prescription that could be filled in a pharmacy was approved in 2012, but restrictions including provider and pharmacist training and certification limited initial uptake.[33] Similar restrictions were approved in Canada as part of the initial 2015 drug approval[9 17] (see box 1).

Nonetheless, mifepristone abortion delivered in primary care settings by physicians and other skilled providers has been shown to be safe and effective.[12–14 28–30 34–36] In this context, we will seek to identify, initiate and evaluate two implementation strategies that aim to overcome clinical, health service and system challenges faced by clinicians adopting mifepristone medical abortion practice, particularly in primary care settings.

Implementation strategy
Community of practice platform

The central iKT strategy for this study is the collaborative interdisciplinary community of practice—with the objective of sharing real-time clinical best practices, disseminating information, advocating for and sharing policy changes to support timely and equitable access to mifepristone medical abortion by bringing together health providers, policy, and system partners and our team of investigators and knowledge users. As Wenger *et al* explain, 'communities of practice are groups of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis.'[37] The principle underlying communities of practice is that practitioners advance their skills and knowledge both on the job and off work through social relationships, rather than in classroom settings.[38] Social learning through a social structure facilitates learning a practice through interactions, relationships and sharing of resources and solutions to build skills and knowledge. The rationale for including a community of practice strategy was derived from the international literature on mifepristone practice in other high-income nations, and was reinforced by findings from focus group research involving Canadian physicians in which we developed and pilot tested the survey for this present study.[39 40]

We created a community of practice platform for the present study: the Canadian Abortion Providers Support-Communauté de pratique canadienne sur l'avortement (CAPS-CPCA), an internet accessible website. It

is designed to encourage multidirectional interaction of healthcare professionals engaging in mifepristone practice with the experts and researchers and will promote sharing best practice resources and facilitators. Interactive pages ('Ask an Expert' and 'Share a Case') will promote a synchronised dialogue while resource pages ('What's happening in your province?', 'Locate a Pharmacy' and 'Helpful Resources') will provide practical, local knowledge for members to apply in their individual practices. Members will be provided news updates on topics relevant to mifepristone practice, such as practice tools, billing codes, regulation changes and universal coverage.

iKT activities

We follow the Canadian Institutes of Health Research definition of iKT, which describes it as 'an approach to doing research that applies the principles of knowledge translation to the entire research process. The central premise of iKT is that involving knowledge users as equal partners alongside researchers will lead to research that is more relevant to, and more likely to be useful to, the knowledge users.'[18] We anticipate that our iKT approach will more rapidly mitigate barriers and improve equitable access to abortion, with the assumption that stakeholders will be more likely to accept and act on coproduced knowledge.[41 42] Using iKT processes to achieve particular objectives focuses researchers and stakeholders on the same page to create shared meaning, identify facilitators and barriers to the process of evidence implementation, and cocreate empirical knowledge to support health service planning. As a result, the partnership process itself is instrumental in implementing sustainable change.[43] The effect of iKT activities on research outcomes such as practice and policy change is still unclear, largely due to inconsistent description, evaluation and reporting in most studies.[44] However, there is emerging evidence from Canada and the UK that iKT may lead to increased capacity to use research among knowledge users, greater relevance and usefulness of research evidence to knowledge users, increased use of research in decision-making, and improved patient and health system outcomes.[45]

In the context of this study, our iKT activities are diverse, responsive and tailored to the needs and contexts of stakeholders. These activities include but are not limited to: invited evidence briefs, face-to-face meetings, media interviews, minutes documenting interactions within monthly multidisciplinary team video-conferenced meetings and an annual national collaboration meeting. Face-to-face interaction will optimise relationships, apprise knowledge users of progress and ensure the flow of ideas. Both clinician and policy-maker knowledge users will be welcomed to join our monthly meetings, to contribute actively to the evaluation and interpretation of data collected each month, and to plan to address identified barriers and facilitators in real time. Knowledge users may identify colleagues for face-to-face meetings relevant to specific phases of the project. Our meeting agendas will address topics from policy development, to education

input, to practice. Our investigators and knowledge users will be invited to convey results to other knowledge user organisations, such as: health professional development at national, provincial and regional health professional meetings; postsecondary institution faculty providing health practitioner education programmes (informing prelicensure training); provincial colleges of health professionals (informing licensure bodies) and community sexual health organisations across Canada. Quarterly briefs will engage team knowledge users, health professional participants, community organisation partners and appropriate colleagues and collaborators identified by them, to encourage informed updated approaches.

Patient and public involvement

Patient partners were involved in codesigning the research questions and outcome measures. Patients and representatives from community-based sexual health organisations across Canada were engaged through a face-to-face symposium in October 2016 and participated in regular monthly videoconference meetings. Through deliberation and dialogue, they discussed with the research team their perspectives on priority areas of study, and recruitment strategies for participants in rural and remote communities. As potential participants did not include patients or members of the public, only healthcare professionals were asked to assess the burden of the intervention and the time required to participate in research. Representatives from community-based sexual health organisations reviewed and provided feedback on our finalised research questions and design during the monthly videoconferences. They will be involved in disseminating study results to the public through infographics shared in presentations and by email with their networks.

Setting and participants

This national study will explore mifepristone medical abortion in the context of primary care settings. In Canada, 85% of Canadians have a regular medical doctor[46] and provision of abortion by primary care providers is highly acceptable—the majority of surgical abortion providers are family physicians.[47] For the purposes of this study, we define primary care settings as any service delivery environment where a prescriber may provide primary care, including hospitals, abortion facilities, health centres, and private physician offices. Consistent with the initial Health Canada approval of the medication, we defined prescriber as a certified physician.

Group A: healthcare professionals engaged with mifepristone practice

Survey and interview enrolment for part 1 of the study is offered to all certified prescribers and pharmacists who intend to begin practice with mifepristone within the first year they are eligible to do so. As our past studies among abortion providers have recruited ~90% of eligible participants,[3 46–48] we anticipate the cohort will be highly

representative. We estimate up to 1000 healthcare professionals would engage in mifepristone practice within the first year.

Group B: community of practice platform
The community of practice website will engage a wide range of interdisciplinary licensed healthcare professionals who are interested in providing mifepristone care, including certified prescribers and pharmacists. We will capture data from all members who enrol in the platform.

Group C: health policy, system, and services decision-makers and non-mifepristone providing healthcare professionals
We will recruit influential decision-makers across Canada who have the potential to impact health policy, system, and service factors found to be important determinants of implementation, as they are identified throughout the study. We will also engage healthcare professionals who do not choose to provide mifepristone, particularly if they are providing similar women's health services, using key informant interviews or focus groups. These non-mifepristone providing healthcare professionals represent a population with an important viewpoint to assist us to understand barriers.

Group D: knowledge users engaged with iKT activities
Knowledge users have been involved in the research process from idea inception (questions and design elements posed by our knowledge user collaborators) to the development of this study to delineate facilitators and inform changes to the health system to facilitate implementation. They include health policy and practice decision-makers at the regional, provincial, and federal levels. We will invite these individuals and organisations to participate in data collection for the evaluation of our iKT activities.

Outcomes
We will evaluate the effect of our mixed-methods, iKT implementation study on health system and policy decision-making, regulatory changes and on uptake of mifepristone. We will assess the uptake of mifepristone medical abortion by measuring the proportion of certified physicians and pharmacists (per professional category) who are providing mifepristone care 1-year post-enrolment, at least once in the most recent 3 months in which they were in their usual practice. In addition, we will explore: (1) the number of communities or populations that have access to abortion compared with baseline; (2) the proportion of certified healthcare professionals providing mifepristone at 6 months post-enrolment (by professional category and by location, eg, urban vs rural, province) and (3) the volume of service provision at 1 year and correlates, particularly compared with baseline distribution of abortion service providers and facilities.

Additionally, based on our mixed-methods analysis, we will develop an empirically driven framework of diffusion of innovation in a health system that builds on and extends Greenhalgh *et al*'s theory.
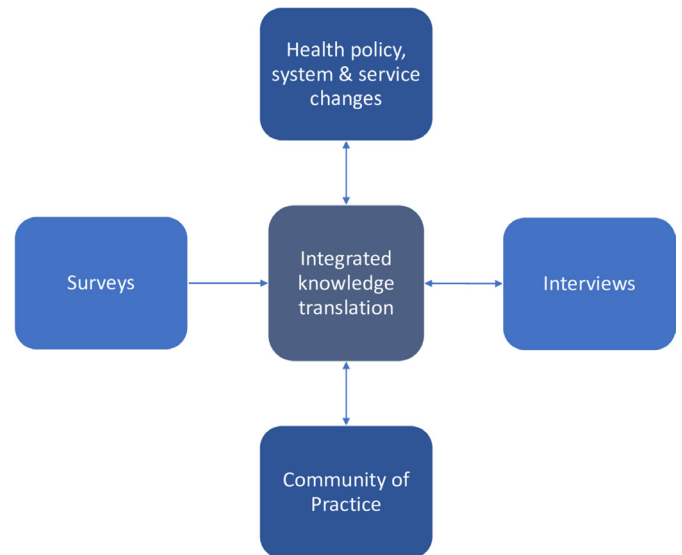

Figure 2 Canada's Mifepristone Implementation Study, components of study design.

We will also be flexible to identify and collect outcomes of interest to our policy-maker stakeholders, as part of our ongoing iKT approach.

Data collection
Our project incorporates five key inter-related evaluation components (figure 2).
1. Continuous iKT activity interactions with key knowledge users and decision-makers in health policy, health system, health professional organisation and regulation, and health services delivery contexts.
2. Evaluation of iKT interactions with knowledge users and decision-makers, and relation to any associated health policy, system and service changes during the project.
3. Surveys and interviews among healthcare professionals who are interested in providing mifepristone care.
4. Quantitative and qualitative data collected from interactions on a community of practice support platform for healthcare professionals, the CAPS-CPCA platform.
5. Interviews with key health system and services decision-makers and informants, and with healthcare professionals who are engaged with women's health but choose not to provide mifepristone care.

Surveys
We will distribute questionnaires among healthcare professionals engaged with mifepristone practice (group A) to measure factors related to adoption of mifepristone abortion into practice[49 50] and to explore constructs for diffusion of innovation. As appropriate, components of either or both sections will be administered at baseline, 6 and 12 months. Participant demographics will be collected at baseline.

Section 1
Component surveys for the constructs of diffusion of innovation will be administered. Constructs that are expected

to change over time will be examined at baseline and later time points (eg, task issues, skills); constructs relating to factors unknown at baseline (eg, characteristics of diffusion) will be collected at 12 months.

Section 2

A 12-item questionnaire adapted from Légaré's validated instrument[51] based on the Godin framework will be administered at baseline, 6 and 12 months.

The survey instruments used in this study were developed and tested following methods described elsewhere.[51 52] Additionally, we conducted a rigorous process to develop and test the surveys used to measure implementation of mifepristone.[40] The process for adapting and pilot testing the surveys for the present study is described in a forthcoming publication.

Interviews

Semistructured interviews will be conducted with a purposeful sample of the certified physicians and pharmacists of group A, selected to represent diversity of: demographic characteristics (eg, gender, age, profession); factors related to adoption and diffusion of mifepristone practice (such as previous abortion practice and rural vs urban location); and positive and negative experiences of abortion practice within 1-year post-training (to investigate the factors that affect implementation). Recruitment will be facilitated via the online survey. All healthcare professionals enrolled in the broader study will be asked, on completing the survey, if they would like to be contacted for a follow-up interview. Interested and eligible physician and pharmacist certificants will be contacted to arrange a follow-up interview in person or by phone. No interview participants will be recruited via group B, the community of practice, although certificants from group A may also be members of the community.

Health policy, system, and services decision-makers and non-mifepristone providing healthcare professionals (group C) and stakeholders involved in our iKT activities (group D) will be purposefully sampled based on preidentified factors[49 53] (eg, profession, previous experience in abortion policy development or service provision, number of years as a knowledge user with the research team) and invited to participate in an interview. Group C participants will be invited via third-party recruitment with the assistance of the study's knowledge user partners. Group D participants will be invited by email to participate in an interview with our research team's implementation scientist. As categories emerge from analysis of transcripts, theoretical sampling will be conducted to pursue emerging themes related to policy, system and/or service factors that influence implementation.

Interview questions will be theoretically informed by diffusion of innovation constructs, and Cook *et al*'s interview guide[22] will be pilot tested with a panel of researchers and clinicians prior to data collection. Interviews will be conducted until we achieve saturation in our data collection, sampling and analysis.[54] In our data collection, we

will seek 'informational redundancy'[55] (new data repeat what was expressed in previous data). We will recruit participants until no new themes or codes are identified in analysis and we have sufficient data to illustrate the core constructs of diffusion of innovation theory. We will also seek to recruit participants until our data sufficiently represent a range of the preidentified factors from our purposeful sampling strategies.

Data collection through the community of practice

Data from the community of practice platform will include reports of barriers and facilitators; responses to iterative one-question polls (based on surveys); questions to experts and participant usage statistics. Relationships within the community of practice and with the research team will enable identification of challenges, which will be shared with knowledge users via the iKT activities listed below.

Evaluation of iKT

To capture and understand the effectiveness of iKT strategies, we will document our activities using the Workgroup for Intervention Development and Evaluation Research reporting checklist[56] as recommended by Gagliardi *et al*.[44] Checklist constructs include: the goal of the activity and iKT partnership, mode of delivery, duration, frequency, participants and personnel. We will also document funding source, who initiated the activity and the theory underpinning the activity. Semistructured interviews with stakeholders, interactions on the community of practice platform and health system, policy, and service changes occurring in real time from our correspondence with knowledge users and decision-makers will help us document the effect of our iKT strategies. As described above, these activities will be diverse and responsive to our knowledge user audiences and may include invited evidence briefs, quarterly briefs, face-to-face meetings, email and phone communication, media interviews, newsletters and minutes of monthly videoconferences.

ANALYSIS
Quantitative data

Survey responses will be summarised descriptively over the entire sample. Stratified analysis will be performed for key determinants (ie, federal, provincial or local according to the issue). For provider characteristics, we will collect data on age, gender, rural versus urban setting, professional role (overall and by specialty), previous abortion provision and independent practice versus working in a setting with two or more abortion providers. In light of Quebec's well-developed support for rural and remote providers,[48 57] we will perform a two-way stratification by (1) Quebec versus the rest of Canada and (2) rural/urban status. Additionally, location data will be collected on all participants to inform geo-mapping analyses on the emergence and diffusion of mifepristone practice (and the subgroups by practitioner and with relation to provincial,

national or regional policies, systems and service structures) throughout Canada. We will analyse interactions of factors using multivariable logistic regression for binary (eg, provision of mifepristone) and ordinal (eg, barriers and facilitators) outcomes and linear multiple regression for volume of service. Emerging results will be used to inform iKT interactions throughout the project.

Following Morse *et al*'s guidance, our mixed-methods design is quantitatively driven with a simultaneous qualitative component.[58] Our survey and CAPS analysis will inform the development of probing questions to ask during interviews. Analysis will be simultaneous using constant comparison methods; qualitative results will be used to enhance description of quantitative results and to corroborate knowledge from our different data sources to clarify key barriers and facilitators.

Qualitative data

Semistructured interviews, open-ended survey questions and CAPS website posted discussions will be subjected to thematic analysis[59] by two qualitatively trained implementation scientists following confidential transcription. Analysis of qualitative data will involve these iterative, concurrent steps:

1. Developing a codebook by identifying contextual codes related to the research objective (identified inductively from the participant data). The two researchers will first code a sample of transcripts independently and compare their results to ensure accurate interpretation of the data. Discrepancies will be resolved through discussion with a third researcher.
2. Identifying individual, organisational and system processes (including patterns, relationships and interactions) between the codes.
3. Organising the processes into a theoretical framework informed by diffusion of innovation constructs. Relevant domains for implementation will be identified through research team discussion and consensus.
4. Writing the analysis into a descriptive, explanatory narrative that illuminates the barriers and facilitators to implementation of mifepristone abortion practice.

We will test and extend the theory of diffusion of innovation. We will consider the frequency of constructs across the data, presence of conflicting constructs and perceived relevance of the constructs on implementation behaviour. Emerging results will be used to inform iKT interactions throughout the project to identify and mitigate addressable barriers.

Analysis of iKT activities data

We will analyse the iKT activity and outcome data, evaluating alignment with theoretical model constructs and addressable barriers identified through the research activities. Qualitative thematic analysis[59] of stakeholder interviews will explore health system and policy factors that influence implementation at regional, provincial and federal levels, as well as the impact of iKT activities on implementation of mifepristone in primary care. As our

additional iKT strategies will be emergent, dynamic and chosen in response to knowledge user and stakeholder need, we will also measure the impact of additional iKT strategies using appropriate methods and outcomes, selection of which will be guided by the Canadian Academy of Health Sciences Impact Framework.[60] All interactions collected will be compared with any subsequent positive, negative or null changes to health system factors that influence implementation of mifepristone. The mechanisms related to any iKT activity will be delineated to assign scaled values for: the impetus (ie, knowledge user, researcher, media/public); the activity; the participants (categorised as per stakeholder groups); results and an assignment of an impact score for the effectiveness of the activity to contribute to changes in health policy, system or service delivery advancing mifepristone care.

ETHICS AND DISSEMINATION

All participants in this study will participate in full informed consent. For survey participants, completion and submission of the survey will constitute implied consent; for interview participants, a signed consent form will be required prior to participation.

Dissemination plan

The study commenced on 1 January 2017 and its expected completion date is 1 January 2020. Full publication of the work will be sought in an international peer-reviewed journal. Findings will be disseminated to research participants through newsletters and media interviews, and to policy-makers through invited evidence briefs, and face-to-face presentations.

DISCUSSION

Knowledge and system improvements generated by this project have the potential to increase the proportion of all abortions that are provided medically. In turn, this could:

► Reduce need and systems costs for surgical abortion.
► Increase delivery of services closer to home, reducing travel and wait times.
► Increase delivery of services by the primary care provider, decreasing the need for referrals.
► Increase abortion safety, as medical abortion can be provided at the earliest and safest stages of pregnancy.
► Increase confidentiality and reduce the need for patients and healthcare providers to face interactions with protesters.
► Benefit hospitals by relieving pressure on operating room time and wait lists, while reducing stigma reported by abortion providers working in operating room settings.

The proposed timely research, undertaken by our well-established cross-sectoral national network, the Contraception and Abortion Research Team-Groupe de recherche sur l'avortement et la contraception,[53 61 62] will

identify the determinants of uptake of medical abortion as this health service innovation is implemented in Canada. We aim to understand, and in real time to address, barriers and facilitators to adoption of this new clinical practice. In addition, we have planned separate studies to assess health outcomes and costs of mifepristone using linked administrative datasets, as well as investigate the role of nurse practitioners and registered midwives in the provision of medical abortion in Canada. Knowledge about the effect of the full range of health policy, system and service determinants on access to mifepristone abortion is needed to realise the potential to increase equitable, safe, confidential abortion care closer to home for women throughout Canada. Findings also will contribute to understanding the mechanisms of iKT relationships and activities that have a meaningful effect on the uptake of evidence into policy and practice.

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REFERENCES
1. Norman WV. Induced abortion in Canada 1974-2005: trends over the first generation with legal access. *Contraception* 2012;85:185–91.
2. Canadian Institute for Health Information. Induced abortions performed in Canada in 2015. Canadian Institutes of Health Information. 2017 http://www.cihi.ca/ (Accessed 30 Mar 2017).
3. Norman WV, Guilbert ER, Okpaleke C, et al. Abortion health services in Canada: Results of a 2012 national survey. *Can Fam Physician* 2016;62:e209–17.
4. Kaposy C. Improving abortion access in Canada. *Health Care Anal* 2010;18:17–34.
5. Dunn S, Cook R. Medical abortion in Canada: behind the times. *CMAJ* 2014;186:13–14.
6. Sethna C, Doull M. Spatial disparities and travel to freestanding abortion clinics in Canada. *Womens Stud Int Forum* 2013;38:52–62.
7. Sethna C, Doull M. Far from home? A pilot study tracking women's journeys to a Canadian abortion clinic. *J Obstet Gynaecol Can* 2007;29:640–7.
8. United Nations Office of the High Commissioner on Human Rights. Convention on the Elimination of All forms of Discrimination against Women, Concluding observtions on the combined eigth and ninth periodic reports of Canada. Committee on the Elimination of Discrimination against Women. 2016 http://www.ohchr.org/EN/HRBodies/CEDAW/Pages/CEDAWIndex.aspx (Accessed 4 May 2018).
9. Health Canada. Regulatory decision summary: MIFEGYMISO. Health Canada. 2015 http://www.hc-sc.gc.ca/ (Accessed 4 May 2018).
10. Health Canada. Health Canada Drug Product Database. Health Canada. 2015 http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php (Accessed 4 May 2018).
11. Jones RK, Henshaw SK. Mifepristone for early medical abortion: experiences in France, Great Britain and Sweden. *Perspect Sex Reprod Health* 2002;34:154–61.
12. Bartlett LA, Berg CJ, Shulman HB, et al. Risk factors for legal induced abortion-related mortality in the United States. *Obstet Gynecol* 2004;103:729–37.
13. Oppegaard KS, Qvigstad E, Fiala C, et al. Clinical follow-up compared with self-assessment of outcome after medical abortion: a multicentre, non-inferiority, randomised, controlled trial. *Lancet* 2015;385:698–704.
14. Løkeland M, Iversen OE, Engeland A, et al. Medical abortion with mifepristone and home administration of misoprostol up to 63 days' gestation. *Acta Obstet Gynecol Scand* 2014;93:647–53.
15. Baird B. Medical abortion in Australia: a short history. *Reprod Health Matters* 2015;23:169–76.
16. Templeton A, Grimes DA. Clinical practice. A request for abortion. *N Engl J Med* 2011;365:2198–204.
17. Health Canada. MIFEGYMISO (mifepristone and misoprostol tablets) - Canadian Distribution and Administration Program. Government of Canada. 2017 http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/63330a-eng.php (Accessed 4 May 2018).
18. Canadian Institutes of Health Research. Guide to knowledge translation planning at CIHR: integrated and end-of-grant approaches. 2012 http://www.cihr-irsc.gc.ca/e/45321.html (Accessed 4 May 2018).
19. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* 2004;82:581–629.
20. Pinnock H, Barwick M, Carpenter CR, et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ* 2017;356:i6795.
21. Rogers EM. *Diffusion of innovation*. 5th ed. New York, NY, USA: Simon Schuster, 2003.

22. Cook JM, O'Donnell C, Dinnen S, *et al*. Measurement of a model of implementation for health care: toward a testable theory. *Implement Sci* 2012;7:59.
23. Godin G, Bélanger-Gravel A, Eccles M, *et al*. Healthcare professionals' intentions and behaviours: a systematic review of studies based on social cognitive theories. *Implement Sci* 2008;3:36.
24. Ajzen I. The theory of planned behavior. *Organ Behav Hum Decis Process* 1991;50:179–211.
25. Triandis HC. Values, attitudes, and interpersonal behavior. *Nebr Symp Motiv* 1980;27:195–259.
26. Aiyer AN, Ruiz G, Steinman A, *et al*. Influence of physician attitudes on willingness to perform abortion. *Obstet Gynecol* 1999;93:576–80.
27. World Health Organization. WHO Model List of Essential Medicine [Internet]. 2017 http://www.who.int/medicines/publications/essentialmedicines/en/ (Accessed 4 May 2018).
28. Kulier R, Gülmezoglu AM, Hofmeyr GJ, *et al*. Medical methods for first trimester abortion. *Cochrane Database Syst Rev* 2004;2:CD002855.
29. Kapp N, Whyte P, Tang J, *et al*. A review of evidence for safe abortion care. *Contraception* 2013;88:350–63.
30. Barnard S, Kim C, Park MH, *et al*. Doctors or mid-level providers for abortion. *Cochrane Database Syst Rev* 2015;7:CD011242.
31. Finer L, Fine JB. Abortion law around the world: progress and pushback. *Am J Public Health* 2013;103:585–9.
32. Raymond EG, Blanchard K, Blumenthal PD, *et al*. Mifeprex REMS Study Group. Sixteen Years of Overregulation: Time to Unburden Mifeprex. *N Engl J Med* 2017;376:790–4.
33. Grossman D, Goldstone P. Mifepristone by prescription: a dream in the United States but reality in Australia. *Contraception* 2015;92:186–9.
34. White K, Carroll E, Grossman D. Complications from first-trimester aspiration abortion: a systematic review of the literature. *Contraception* 2015;92:422–38.
35. Winikoff B, Westhoff C. Fifteen years: looking back and looking forward. *Contraception* 2015;92:177–8.
36. Kopp Kallner H, Gomperts R, Salomonsson E, *et al*. The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomised controlled equivalence trial. *BJOG* 2015;122:510–7.
37. Wenger E, McDermott R, Snyder WM. *Cultivating communities of practice*. Boston: Harvard Business School Publishing, 2002.
38. Li LC, Grimshaw JM, Nielsen C, *et al*. Evolution of Wenger's concept of community of practice. *Implement Sci* 2009;4:11.
39. 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* 2016;56:648–54.
40. Devane C, Renner R, Munro S, *et al*. *Implementation of Mifepristone in Canadian Medical Abortion Care: Pilot and Feasibility Testing of a Survey to Assess Facilitators and Barriers*. Vancouver, BC: Contraception and Abortion Research Team, 2019.
41. Kothari A, Armstrong R. Community-based knowledge translation: unexplored opportunities. *Implement Sci* 2011;6:59.
42. Harrison MB, Légaré F, Graham ID, *et al*. Adapting clinical practice guidelines to local context and assessing barriers to their use. *CMAJ* 2010;182:E78–84.
43. Harrison MB, Graham ID. Roadmap for a participatory research-practice partnership to implement evidence. *Worldviews Evid Based Nurs* 2012;9:210–20.
44. Gagliardi AR, Berta W, Kothari A, *et al*. Integrated knowledge translation (IKT) in health care: a scoping review. *Implement Sci* 2016;11:38.
45. Graham ID, Kothari A, McCutcheon C. Integrated Knowledge Translation Research Network Project Leads. Moving knowledge into action for more effective practice, programmes and policy: protocol for a research programme on integrated knowledge translation. *Implement Sci* 2018;13:22.
46. Statistics Canada. Access to a regular medical doctor, 2014. Government of Canada. 2015 https://www.statcan.gc.ca/pub/82-625-x/2015001/article/14177-eng.htm (Accessed 4 May 2018).
47. Norman WV, Guilbert ER, Okpaleke C, *et al*. Abortion health services in Canada: Results of a 2012 national survey. *Can Fam Physician* 2016;62:300.
48. Guilbert ER, Hayden AS, Jones HE, *et al*. First-trimester medical abortion practices in Canada: National survey. *Can Fam Physician* 2016;62:e201–8.
49. Norman WV, Soon JA, Maughn N, *et al*. Barriers to rural induced abortion services in Canada: findings of the British Columbia Abortion Providers Survey (BCAPS). *PLoS One* 2013;8:e67023.
50. Dressler J, Maughn N, Soon JA, *et al*. The perspective of rural physicians providing abortion in Canada: qualitative findings of the BC Abortion Providers Survey (BCAPS). *PLoS One* 2013;8:e67070.
51. Légaré F, Borduas F, Freitas A, *et al*. Development of a simple 12-item theory-based instrument to assess the impact of continuing professional development on clinical behavioral intentions. *PLoS One* 2014;9:e91013.
52. Guilbert ER, Morin D, Guilbert AC, *et al*. Task-shifting in the delivery of hormonal contraceptive methods: validation of a questionnaire and preliminary results. *Int J Nurs Pract* 2011;17:315–21.
53. Hulme J, Dunn S, Guilbert E, *et al*. Barriers and facilitators to family planning access in Canada: Stakeholder input on implications for health system and policy reform. *Healthcare Policy* 2015;10:48–63.
54. Saunders B, Sim J, Kingstone T, *et al*. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant* 2018;52:1–15.
55. Sandelowski M. Sample size in qualitative research. *Res Nurs Health* 1995;18:179–83.
56. Albrecht L, Archibald M, Arseneau D, *et al*. Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. *Implement Sci* 2013;8:52.
57. Guilbert ER, Robitaille J, Guilbert AC, *et al*. Determinants of the implementation of a new practice in hormonal contraception by Quebec nurses. *Can J Hum Sex* 2014;23:34–48.
58. Morse J, Neihaus L, Wolfe R, *et al*. The role of the theoretical drive in maintaining validity in mixed-methods research. *Qualitative Research in Psychology* 2006;3:279–91.
59. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
60. Panel on Return on Investment in Health Research. Making an impact: a preferred framework and indicators to measure returns on investment in health research. *Canadian Academy of Health Sciences* 2009.
61. University of British Columbia. Contraception and Abortion Research Team - Groupe de recherche su l'avortement, et al. contraception (CART-GRAC). *Team and Network* 2017 www.cart-grac.ubc.ca (Accessed 4 May 2018).
62. Norman WV, Shoveller JA, Kaczorowski J. Contraception and Abortion in BC: Experience guiding research guiding care. Richmond, BC. 2011 http://med-fom-cart-grac.sites.olt.ubc.ca/files/2015/08/CART2011ProceedingsFinal.pdf (Accessed 4 May 2018).