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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 & Analysis

This prospective mixed-methods implementation study will involve a national sample of physicians and pharmacists recruited via an online training program, 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, 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 & 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.

ARTICLE SUMMARY

Strengths and limitations of this study

- This study will provide critical evidence about the effect of the full range of health policy, system, and service determinants on access to medication abortion.
- We will employ an integrated knowledge translation approach (iKT), where decision makers and practitioners are actively involved in collecting, analyzing, and interpreting our study data.
- We anticipate that our iKT approach of having decision makers on the research team will have the potential to accelerate the implementation of mifepristone in Canada, as decision makers will be more likely to accept and act on our co-produced knowledge, more rapidly mitigate barriers, and improve equitable access to abortion.
- Results will be generalizable to other nations that have similar abortion restrictions for medication abortion.

INTRODUCTION

Induced abortion is a common, safe, and legal reproductive health procedure in Canada, 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, mostly 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 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 January 10th, 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 to surgical.[11] Widely differing rates of mifepristone implementation, particularly in primary care settings, have been noted world-wide 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 to 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 geographic 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 program.[9,17] Our multidisciplinary research team theorizes 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 hypothesize 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?

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 organizations to reduce barriers, and optimize facilitators, for mifepristone abortion practice.

This study protocol is guided by the Standards for Reporting Implementation Studies (StaRI) 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 (e.g. 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.* operationalized these constructs into semi-structured survey and interview questions to allow researchers to generate evidence on barriers and enablers to implementation.[22]

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

Within these constructs we further explore provider uptake and behaviours using *Godin'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 practice 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 two years of practice in Canada. We hypothesized 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 comprised of senior, mid, and early career investigators, national and provincial policy makers, health care and health professional organizations, 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 mcg tablets). Mifepristone is used in more than 60 countries worldwide, is on the World Health Organization 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 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 Table 1).

Table 1. Canadian Restrictions for Prescribing and Dispensing Mifepristone, July 2015 [9,17]

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

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

A. 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 explains, "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 web site. It is designed to encourage multi-directional 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 asynchronized 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.

B. Integrated knowledge translation 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 co-produced 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 co-create 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 at annual national collaboration meetings. Face-to-face interaction will optimize 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 organizations, such as: health professional development at national, provincial, and regional health professional meetings; post-secondary institution faculty providing health practitioner education programs (informing pre-licensure training); provincial colleges of health professionals (informing licensure bodies); and community sexual health organizations across Canada. Quarterly briefs will engage team knowledge users, health professional participants, community organization partners, and appropriate colleagues and collaborators identified by them, to encourage informed updated approaches.

Patient and Public Involvement

Patient partners were involved in co-designing the research questions and outcome measures. Patients and representatives from community-based sexual health organizations across Canada were engaged through a face-to-face symposium in October 2015 and participated in regular monthly video-conference 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 health care professionals were asked to assess the burden of the intervention and the time required to participate in research. Representatives from community-based sexual health organizations reviewed and provided feedback on our finalized 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 enrollment 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 1,000 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 enroll in the platform.

Group C: Health policy, system, and services decision makers and non-mifepristone providing health care 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 health care 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 health care 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 organizations 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 upon 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 enrollment, 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 to baseline; 2) the proportion of certified healthcare professionals providing mifepristone at 6 months post enrollment (by professional category and by location, e.g. urban vs rural, province); and 3) the volume of service provision at 1-year and correlates, particularly compared to 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 Greenhlagh *et al.*'s theory.

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 organization and regulation, and health services delivery contexts; and

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 Canadian Abortion Providers Support- Communaute de pratique Canadienne sur l'avortement (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;

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

1. 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 [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 (e.g., task issues, skills); constructs relating to factors unknown at baseline (e.g., 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.

2. Interviews: Semi-structured interviews will be conducted with a purposeful sample of the certified physicians and pharmacists of Group A, selected to represent diversity of: demographic characteristics (e.g. 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, upon 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 health care professionals (Group C) and stakeholders involved in our iKT activities (Group D) will be purposefully sampled based on pre-identified factors [49,53] (e.g. 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 represents a range of the pre-identified factors from our purposeful sampling strategies.

3. Data Collection through the Community of Practice: Data from the community of practice platform will include reports of barriers and facilitators; responses to iterative 1-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.

4. Evaluation of Integrated Knowledge Translation

To capture and understand the effectiveness of iKT strategies we will document our activities using the Workgroup for Intervention Development and Evaluation Research (WIDER) 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. Semi-structured 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

1. Quantitative Data

Survey responses will be summarized descriptively over the entire sample. Stratified analysis will be performed for key determinants (i.e., Federal, Provincial, or Local according to the issue). For provider characteristics we will collect data on age, gender, rural vs urban setting, professional role (overall and by specialty), previous abortion provision, and independent practice vs 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 a) Quebec vs the rest of Canada and b) 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 sub-groups by practitioner and with relation to provincial, national, or regional policies, systems, and service structures) throughout Canada. We will analyze interactions of factors using multivariable logistic regression for binary (e.g. provision of mifepristone) and ordinal (e.g. 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'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.

2. Qualitative Data

Semi-structured 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, organizational, and system processes (including patterns, relationships, and interactions) between the codes.
3) Organizing 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.

3. Analysis of Integrated Knowledge Translation 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 (i.e., knowledge user, researcher, media/public); the activity; the participants (categorized 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

Ethical approval was obtained from the University of British Columbia Children's and Women's Hospital Research Ethics Review Board (H16-01006) prior to enrollment of participants. 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 January 1, 2017 and its expected completion date is January 1, 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 health care 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 & Abortion Research Team-Groupe de recherche sur l'avortement et la contraception (CART-GRAC),[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. Knowledge about the effect of the full range of health policy, system and service determinants on access to mifepristone abortion is needed to realize 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 uptake of evidence into policy and practice.

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AUTHORS' CONTRIBUTIONS

WVN, EG and SD developed the study concept and approach with input from all co-authors. WVN wrote the first draft of the manuscript. SM significantly contributed to the design of iKT approach and qualitative interviews, and led all manuscript revisions. EG, SD and RR significantly contributed to the survey design and WVN, SD and EG to the structure and content of the Community of Practice platform. TK contributed to the design of the iKT approach. JAS led the design of the pharmacist recruitment and data collection. MB, CD, RR, AW and MSW contributed to study design and practitioner support elements. All authors contributed to manuscript revisions and reviewed and approved the final manuscript.

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COMPETING INTERESTS STATEMENT

The authors declare that they have no competing interests.

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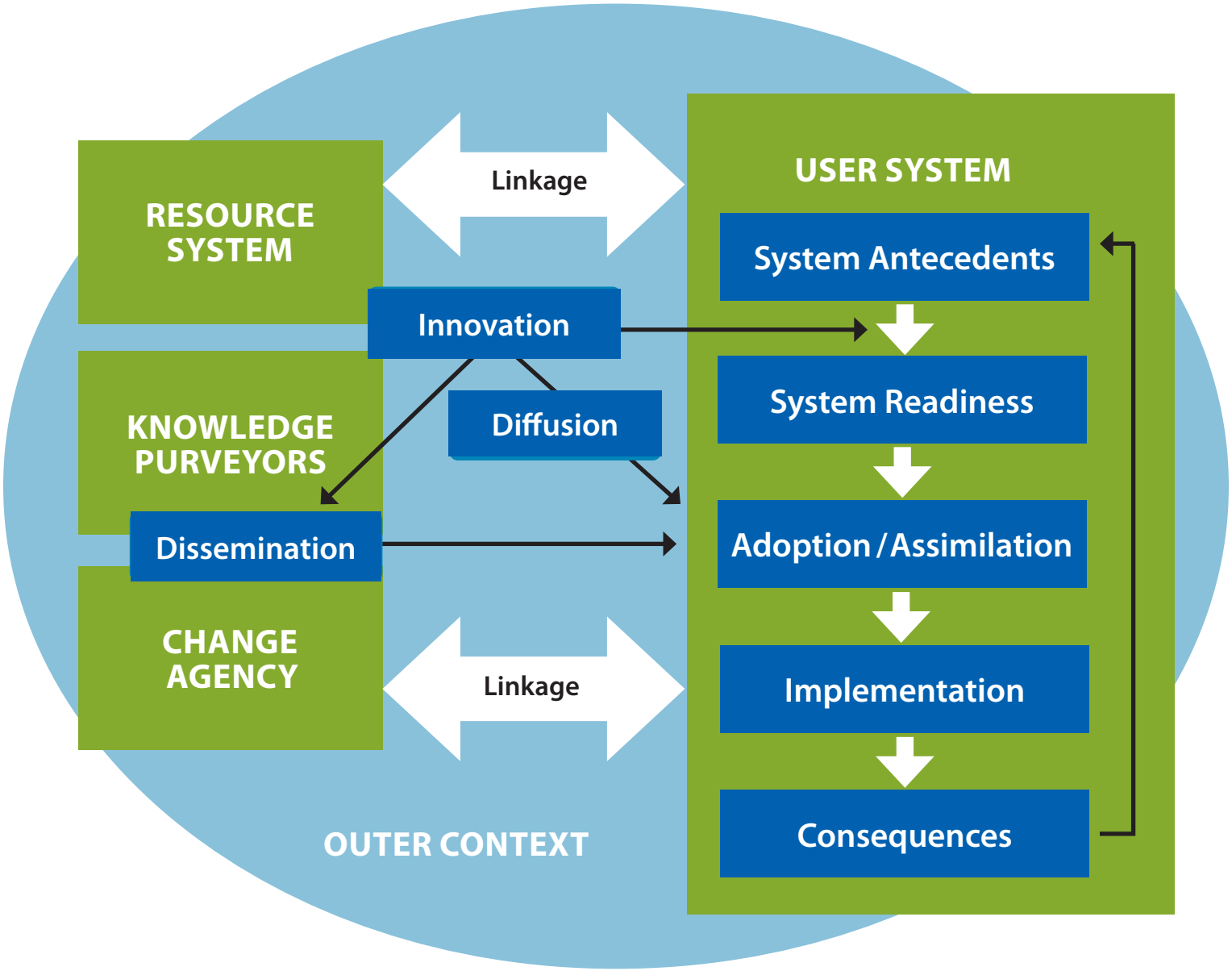
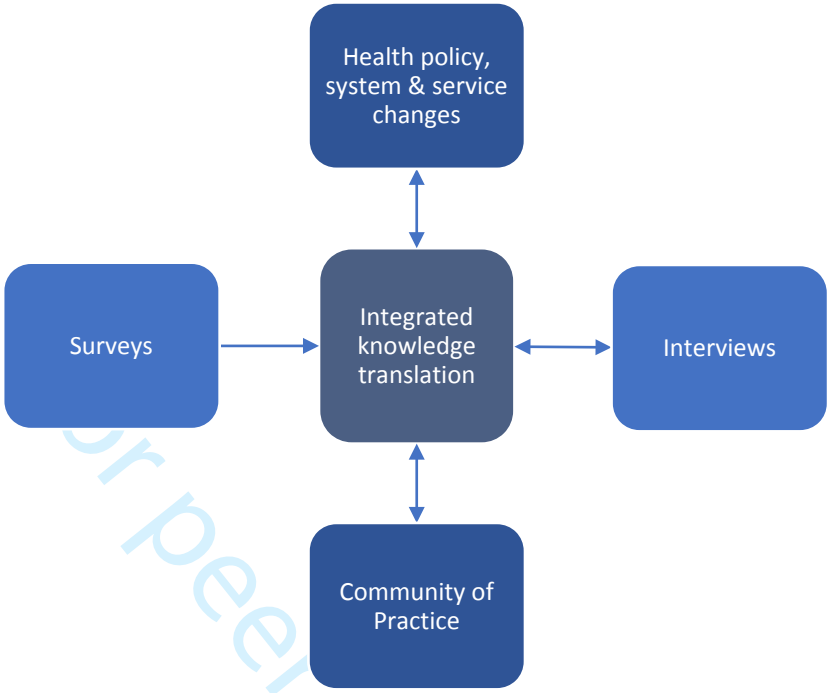


A Conceptual Model of Diffusion of Innovations in Health Service Delivery and Organizations, adapted from Greenhalgh et al. (2004)



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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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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 & Analysis

This prospective mixed-methods implementation study will involve a national sample of physicians and pharmacists recruited via an online training program, 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, 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 & 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.

ARTICLE SUMMARY

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, analyzing, 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 co-produced knowledge, mitigating barriers, and improving equitable access to abortion.

INTRODUCTION

Induced abortion is a common, safe, and legal reproductive health procedure in Canada, 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, mostly 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 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 January 10th, 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 to surgical.[11] Widely differing rates of mifepristone implementation, particularly in primary care settings, have been noted world-wide 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 to 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 geographic 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 program.[9,17] Our multidisciplinary research team theorizes 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 hypothesize 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?

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 organizations to reduce barriers, and optimize facilitators, for mifepristone abortion practice.

This study protocol is guided by the Standards for Reporting Implementation Studies (StaRI) 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 (e.g. 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.* operationalized these constructs into semi-structured survey and interview questions to allow researchers to generate evidence on barriers and enablers to implementation.[22]

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

Within these constructs we further explore provider uptake and behaviours using *Godin'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 practice 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 two years of practice in Canada. We hypothesized 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 comprised of senior, mid, and early career investigators, national and provincial policy makers, health care and health professional organizations, 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 mcg tablets). Mifepristone is used in more than 60 countries worldwide, is on the World Health Organization 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 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 Table 1).

Table 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

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

A. 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 explains, "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 web site. It is designed to encourage multi-directional 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 asynchronized 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.

B. Integrated knowledge translation 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 co-produced 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 co-create 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 at annual national collaboration meetings. Face-to-face interaction will optimize 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 organizations, such as: health professional development at national, provincial, and regional health professional meetings; post-secondary institution faculty providing health practitioner education programs (informing pre-licensure training); provincial colleges of health professionals (informing licensure bodies); and community sexual health organizations across Canada. Quarterly briefs will engage team knowledge users, health professional participants, community organization partners, and appropriate colleagues and collaborators identified by them, to encourage informed updated approaches.

Patient and Public Involvement

Patient partners were involved in co-designing the research questions and outcome measures. Patients and representatives from community-based sexual health organizations across Canada were engaged through a face-to-face symposium in October 2015 and participated in regular monthly video-conference 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 health care professionals were asked to assess the burden of the intervention and the time required to participate in research. Representatives from community-based sexual health organizations reviewed and provided feedback on our finalized 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 enrollment 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 1,000 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 enroll in the platform.

Group C: Health policy, system, and services decision makers and non-mifepristone providing health care 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 health care 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 health care 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 organizations 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 upon 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 enrollment, 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 to baseline; 2) the proportion of certified healthcare professionals providing mifepristone at 6 months post enrollment (by professional category and by location, e.g. urban vs rural, province); and 3) the volume of service provision at 1-year and correlates, particularly compared to 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 Greenhlagh *et al.*'s theory.

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 organization and regulation, and health services delivery contexts; and

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 Canadian Abortion Providers Support- Communaute de pratique Canadienne sur l'avortement (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;

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

1. 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 (e.g., task issues, skills); constructs relating to factors unknown at baseline (e.g., 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.

2. Interviews: Semi-structured interviews will be conducted with a purposeful sample of the certified physicians and pharmacists of Group A, selected to represent diversity of: demographic characteristics (e.g. 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, upon 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 health care professionals (Group C) and stakeholders involved in our iKT activities (Group D) will be purposefully sampled based on pre-identified factors [49,53] (e.g. 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 represents a range of the pre-identified factors from our purposeful sampling strategies.

3. Data Collection through the Community of Practice: Data from the community of practice platform will include reports of barriers and facilitators; responses to iterative 1-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.

4. Evaluation of Integrated Knowledge Translation

To capture and understand the effectiveness of iKT strategies we will document our activities using the Workgroup for Intervention Development and Evaluation Research (WIDER) 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. Semi-structured 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

1. Quantitative Data

Survey responses will be summarized descriptively over the entire sample. Stratified analysis will be performed for key determinants (i.e., Federal, Provincial, or Local according to the issue). For provider characteristics we will collect data on age, gender, rural vs urban setting, professional role (overall and by specialty), previous abortion provision, and independent practice vs 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 a) Quebec vs the rest of Canada and b) 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 sub-groups by practitioner and with relation to provincial, national, or regional policies, systems, and service structures) throughout Canada. We will analyze interactions of factors using multivariable logistic regression for binary (e.g. provision of mifepristone) and ordinal (e.g. 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'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.

2. Qualitative Data

Semi-structured 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, organizational, and system processes (including patterns, relationships, and interactions) between the codes.
3) Organizing 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.

3. Analysis of Integrated Knowledge Translation 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 (i.e., knowledge user, researcher, media/public); the activity; the participants (categorized 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

Ethical approval was obtained from the University of British Columbia Children's and Women's Hospital Research Ethics Review Board (H16-01006) prior to enrollment of participants. 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 January 1, 2017 and its expected completion date is January 1, 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 health care 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 & Abortion Research Team-Groupe de recherche sur l'avortement et la contraception (CART-GRAC),[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 realize 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 uptake of evidence into policy and practice.

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AUTHORS' CONTRIBUTIONS

WVN, EG and SD developed the study concept and approach with input from all co-authors. WVN wrote the first draft of the manuscript. SM significantly contributed to the design of iKT approach and qualitative interviews, and led all manuscript revisions. EG, SD and RR significantly contributed to the survey design and WVN, SD and EG to the structure and content of the Community of Practice platform. TK contributed to the design of the iKT approach. JAS led the design of the pharmacist recruitment and data collection. MB, CD, RR, AW and MSW contributed to study design and practitioner support elements. All authors contributed to manuscript revisions and reviewed and approved the final manuscript.

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COMPETING INTERESTS STATEMENT

The authors declare that they have no competing interests.

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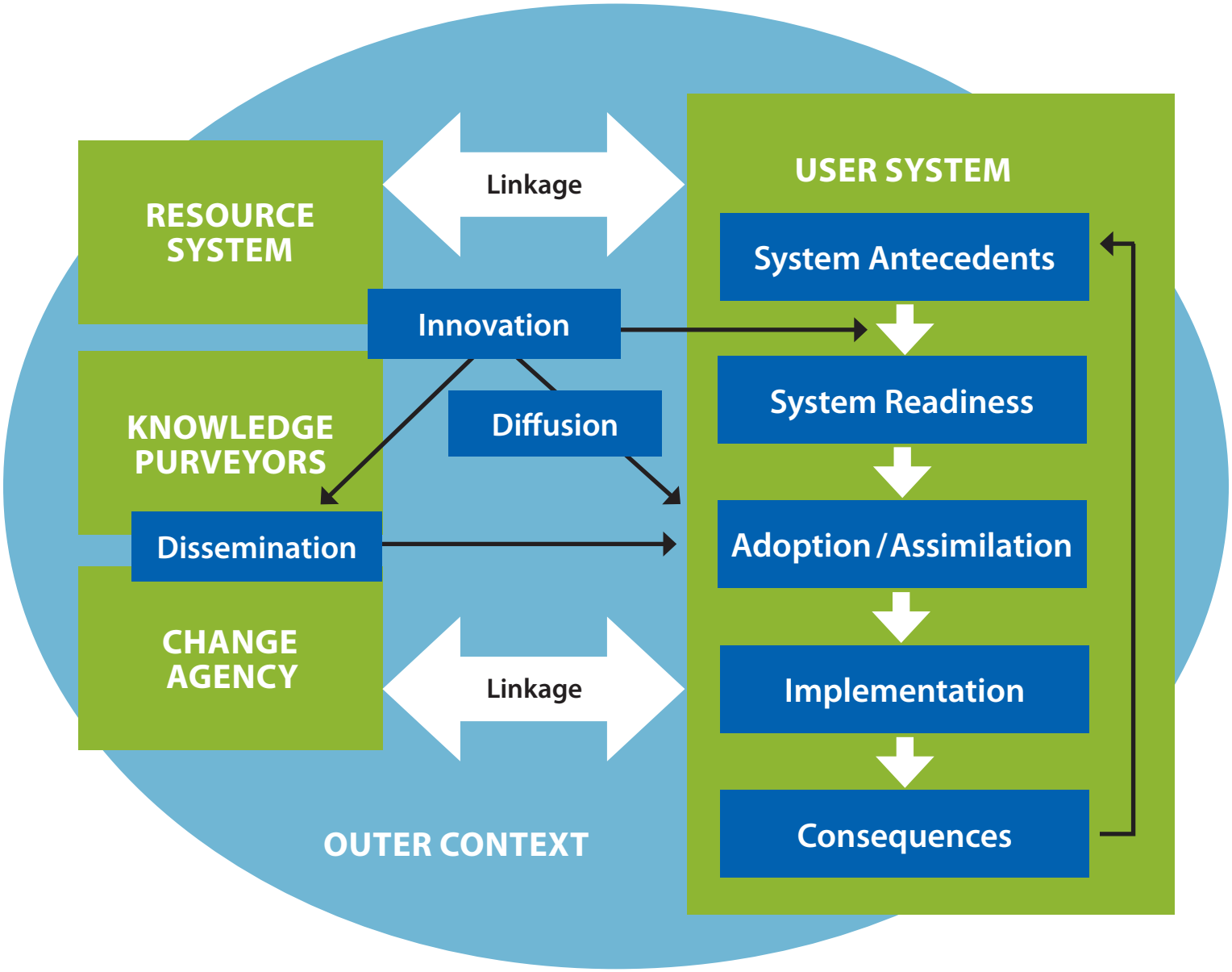

A Conceptual Model of Diffusion of Innovations in Health Service Delivery and Organizations, adapted from Greenhalgh et al. (2004)