Exploring the regulatory journey of progestin-only emergency contraceptive pills in Canada: A multi-methods study

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Abstract

The journey of emergency contraception in Canada serves as a noteworthy example of drug deregulation in the sexual and reproductive health field. Over less than two decades, progestin-only emergency contraceptive pills transitioned from being a Schedule I drug requiring a prescription from a physician to being available over-the-counter as a Schedule III drug. Through a scoping review and a mystery client study in Greater Ottawa, this thesis aims to explore the regulatory reform pathway of progestin-only emergency contraceptive pills and evaluate the current availability and accessibility of both the progestin-only and ulipristal acetate forms of emergency contraception. The findings from the scoping review shed light on the process of reproductive health drug deregulation in Canada and provide a model for how a change in regulatory status might be successful for other medications with similar safety and efficacy profiles. The results from the mystery client study showcase the implementation challenges once deregulation has gone into effect. The findings highlight the need for continued education of and engagement with pharmacists and pharmacy staff. The journey of progestin-only emergency contraception offers important lessons for what the deregulation of medication abortion drugs might entail.

Résumé

Le parcours de la contraception d'urgence au Canada constitue un exemple remarquable de déréglementation des médicaments dans le domaine de la santé sexuelle et reproductive. En moins de deux décennies, les pilules contraceptives d'urgence à base de progestatif sont passées d'un médicament nécessitant une ordonnance d'un médecin à un médicament disponible en vente libre. À travers une revue de la littérature et une étude de client mystère dans la région d'Ottawa, cette thèse vise à examiner le parcours de la réforme réglementaire des pilules contraceptives d'urgence à base de progestatif et à évaluer la disponibilité actuelle et l'accessibilité tant des formes à base de progestatif que de la pilule contraceptive d'urgence sous le nom d'acétate d'ulipristal. Les résultats de la revue de la littérature éclairent le processus de déréglementation des médicaments liés à la santé reproductive au Canada et proposent un modèle pour la réussite d'un changement de statut réglementaire pour d'autres médicaments présentant des profils de sécurité et d'efficacité similaires. Les résultats de l'étude de client mystère mettent en valeur les défis de mise en œuvre une fois que la déréglementation est entrée en vigueur, soulignant le besoin d'une éducation continue et d'une interaction avec les pharmaciens et le personnel pharmaceutique. Le parcours de la contraception d'urgence à base de progestatif offre également des leçons importantes sur ce que pourrait impliquer la régulation des médicaments pour l'avortement.

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List of acronyms and abbreviations

ASEC	American Society for Emergency Contraception
BTC	Behind-the-counter
CE	Continuing education
CPhA	Canadian Pharmacists Association
EC	Emergency contraception
ECP	Emergency contraceptive pill
IUD	Intrauterine device
JOGC	Journal of Obstetrics and Gynaecology Canada
LH	Luteinizing hormone
LNG-EC	Levonorgestrel emergency contraception
NAPRA	National Association of Pharmacy Regulatory Authorities
OC	Oral contraceptive
OCP	Ontario College of Pharmacists
OTC	Over-the-counter
PI	Principal investigator
REB	Research Ethics Board
UPA	Ulipristal acetate

Chapter 1: Introduction

Background and context

General overview of emergency contraception

Emergency contraceptives encompass medications or devices employed after sexual activity to reduce the risk of pregnancy (Pancham & Dunn, 2007). These post-coital contraceptives are utilized in cases of contraceptive method failure, whether ongoing or pre-coital or when no contraception was employed during penile-vaginal intercourse. As of 2024, two main modalities of emergency contraception (EC) are globally available: intrauterine device (IUD) insertion and a variety of orally administered pharmaceuticals. The medications used for post-coital pregnancy prevention belong to diverse drug classes, each operating through distinct mechanisms of action (Trussell, 2012). Notably, all forms of EC can be administered up to three days after sexual intercourse. These methods encompass the Yuzpe method (combined oral contraceptive (OC) pills), the copper-T intrauterine device (IUD), progestin-only EC pills, ulipristal acetate (UPA), and low-dose mifepristone (Ederman,2012).

The history of emergency contraception spans over five decades, marked by significant advancements in methods, mechanisms of action, timing of use, side effects, and efficacy. The exploration of contraception began in the 1920s when the correlation between high estrogen levels and the prevention of pregnancies was discovered (Ellertson, 1996). A notable milestone in EC history occurred in the Netherlands, where a groundbreaking report was published detailing the post-coital administration of high dosages of estrogen to a teenage rape survivor (Glasier et al., 1996). In Canada, the landscape for emergency contraception experienced a pivotal shift with the decriminalization of contraceptives and the (partial) legalization of abortion in 1969 through Bill C-150. The 1970s witnessed the global introduction of the Yuzpe method, named after Canadian gynecologist Albert Yuzpe (Foster & Wynn, 2012). This method, widely recognized as a pioneering development, played a crucial role in shaping the early landscape of emergency contraception.

During the 1970s and 1980s, information about the Yuzpe method was disseminated through word-of-mouth and women's health collectives in North America. Women began creating their post-coital contraceptives by using and sharing packages of combined hormonal oral contraceptive pills. However, a notable development occurred in the 1980s when a dedicated product briefly entered the market in both the United States and Canada, offering a more standardized and accessible form of emergency contraception.

Because the Yuzpe method can be created from “standard” OC pills, it is the most widely available form of emergency contraception worldwide. However, it is also the least effective; when used within the first 72 hours after unprotected or under-protected sex, the Yuzpe method reduces the risk of pregnancy by up to 75%. Because the principal mechanism of action involves delaying ovulation, it is most effective when used immediately after sex (Trussell et al., 1998). Although the Yuzpe method is extremely safe and serious adverse events are negligible, the main side effects are nausea and vomiting; vomiting within 30 minutes of using the Yuzpe will reduce efficacy unless more pills are taken (Grimes et al., 1998). Although this method of EC is no longer widely used, it remains an important option for those who do not have access to other forms of post-coital contraception and there are no absolute contraindications to use.

In the 1970s researchers also began to investigate the use of the copper-T IUD as a method of post-coital pregnancy prevention (Cleland et al., 2014). The IUD represents a highly effective and long-acting reversible contraception option (Black et al., 2016), surpassing emergency contraceptive pills in their efficacy for preventing pregnancy (Edwards et al., 2018). Intrauterine devices are available in two forms: the copper IUD and the hormonal IUD.
The hormonal IUD releases progestin to prevent pregnancy and remains effective for up to 5 years after insertion (Ti et al., 2020). The copper IUD, commonly recognized in Canada as ParaGard®, introduces copper into the uterine environment. This action establishes an unfavorable condition for sperm, thereby proficiently inhibiting fertilization (Black et al., 2016).

(Black et al., 2016). With a reported efficacy of 99%, (Edwards et al., 2018; Shen et al., 2019; Cleland et al., 2012), the copper IUD stands out as a safe and highly effective contraceptive method with a duration of use of up to 10 years post-insertion (Edwards et al., 2018). Importantly, it can be inserted up to 10 days following under-protected intercourse (Cleland et al., 2012; Harper et al., 2012), providing a valuable non-pill form of emergency contraception that acts as a bridge to ongoing contraception and is cost-effective.

A pivotal turning point in the history of emergency contraception emerged with the discovery that progestin-only pills could effectively be used post-coitus to reduce the risk of pregnancy. These pills, containing 1.5 mg of the synthetic progesterone levonorgestrel, are to be taken within five days after unprotected sex and exhibit up to 89% efficacy in preventing pregnancy when used as directed (Trussell, 2012). However, there is some evidence that indicates that the efficacy of progestin-only EC is lower when used by women weighing more than 165 pounds (Vogel, 2015). Progestin-only emergency contraceptive pills (ECPs) primarily function by delaying ovulation, but if the egg has already been released the medication can also impede fertilization (Trussell, 2012). Research indicates minimal impact on the endometrium and confirms that they do not terminate an existing pregnancy (Ho, 2000). The most commonly reported side effects of this medication include nausea and vomiting (Croxatto et al., 2001).

The World Health Organization (WHO) emphasizes that the benefits of progestin-only ECPs far outweigh any potential risks, with no reported deaths associated with their use (WHO, 2019). Consequently, these pills are available without a prescription in numerous countries worldwide, either over the counter or behind the counter (World Health Organization, 2021). Progestin-only ECPs are integral to global standards of care guidelines for managing clinical cases of rape and are classified as essential medicines (Gatter et al., 2015). Notably, these pills are typically available as dedicated products, explicitly labeled, dosed, marketed, and sold for their post-coital purpose. Importantly, progestin-only EC can also be derived from progestin-only oral contraceptives.

Recognized as the second generation of EC medication, ulipristal acetate is a selective progesterone-receptor modulator, distinguished for its superior efficacy and reciprocal safety compared to levonorgestrel. Although Health Canada originally approved a low-dose form of UPA to treat uterine fibromas, in 2015 the agency approved UPA as an emergency contraception regimen under the brand name Ella (Vogel, 2015). It is now recommended as the first-line treatment for emergency contraception (Rosato et al., 2016). Rapidly absorbed by the body, UPA acts by inhibiting or delaying ovulation (McKeage & Croxtall, 2011; Rosato et al., 2016).

Typically prescribed at a 30 mg dosage, the medication must be taken within the initial five days (120 hours) after intercourse to effectively prevent pregnancy (Brache et al., 2010; McKeage & Croxtall, 2011) and it maintains its efficacy over time. Studies indicate that UPA can reduce the risk of pregnancy by up to 89% (Trussell, 2012). Additionally, it has demonstrable efficacy in women with a BMI over 30 (Vogel, 2015). Although UPA is available over-the-counter or behind-the-counter in a number of countries, including most countries in Western Europe, it remains a prescription-only drug in North America. Women with a history of blood clots are recommended to opt for progestin-only EC, UPA, or the copper-T IUD instead of combined ECPs.

Mifepristone and misoprostol are hailed as the gold standard for medication abortion, proving exceptionally safe and effective in terminating early pregnancies (Gatter et al., 2015). Moreover, mifepristone, when administered in lower doses, can also function as emergency contraception (EC), albeit this form of EC is only accessible in a handful of countries like Armenia, China, Russia, and Vietnam. Its efficacy is particularly noteworthy when taken within 72 to 120 hours following unprotected or under-protected intercourse (Grimes et al., 1998). Typically prescribed in dosages ranging from 10 to 25 mg, mifepristone acts as a progesterone antagonist, effectively blocking or delaying ovulation and exhibiting fewer side effects compared to traditional methods of emergency contraception (Rosato et al., 2016; Liu et al., 1987).

Mifepristone serves a dual function: it acts as a preventive measure against unwanted pregnancies at lower doses and as an abortifacient at higher doses. Additionally, higher dosages have the capability to delay menstruation (Grimes et al., 1998). While in Canada, mifepristone is sanctioned solely as an abortifacient, typically administered as part of a combination package with a second drug, misoprostol, it is not approved for use as an emergency contraceptive.

Emergency contraception in the global context

Emergency contraception has been utilized worldwide for decades, serving as a vital tool in mitigating the risk of unintended pregnancy. Over 150 countries offer emergency contraceptive pills, with more than 60 of these providing progestin-only options, and a global market boasting over 100 brands (ICEC, 2019; Foster & Wynn, 2012). Numerous organizations have spearheaded initiatives to promote the widespread accessibility of emergency contraception on a global scale, acknowledging its crucial role in safeguarding individuals against pregnancies that could jeopardize their health and overall well-being (Casey et al., 2015). However, the regulatory landscape of EC is intricately tied to political and healthcare system reforms within individual countries (Foster & Wynn, 2012). Although emergency contraception empowers women to assert control over their reproductive health and rights (Spencer, 2001), EC remains inaccessible in many countries (Guttmatcher Institute, 2013).

Debates surrounding ethical issues have caused barriers to accessing emergency contraception. In many places, particularly those where Catholic or Evangelical Christians have political power, a conflation of progestin-only ECPs with abortion has stymied availability (Wynn et al., 2007a). Medical professionals and journalists also sometimes incorrectly state that progestin-only ECPs have a post-implantation effect, contributing to confusion about the mechanism of action (Ederman, 2012). The label on many progestin-only ECP products has

also long reported that there is a possible post-fertilization effect which has contributed to policies and regulations that limit access. Despite religious and socio-cultural debates about what constitutes an abortifacient, medical authorities assert that pregnancy is defined from implantation onwards (Society of Obstetricians and Gynecologists of Canada, n.d.).

More than 40% of women globally will have an unintended pregnancy over the course of their reproductive lives (Dailard, 1999). A study conducted by the World Health Organization in 36 countries revealed that over 66% of sexually active women discontinued contraception due to misconceptions and negative attitudes towards side effects (WHO, n.d.). This includes consistent and persistent misinformation about various forms of emergency contraception. Enhancing the accessibility and availability of emergency contraception becomes imperative to address this lack of knowledge and awareness (Wynn et al., 2007b).

The ongoing challenges exacerbated by the COVID-19 pandemic further underscore the urgency of expanding access to emergency contraception. The United National Population Fund estimated that 12 million women globally experienced contraceptive access interruptions due to the pandemic, resulting in 1.4 million unintended pregnancies (UNFPA, 2020). These disruptions highlight the life-altering consequences of compromised contraceptive access, emphasizing the need for resilient and adaptable strategies to ensure the availability of emergency contraception on a global scale.

Contraception and unintended pregnancy in Canada

Despite the longstanding availability of emergency contraception as a safe and effective option to prevent unintended pregnancies, its underutilization remains a concern in Canada, contributing to the risks of unintended pregnancies (Chaumont & Foster, 2016). Statistics Canada reveals that around 24.9% of non-pregnant women who expressed a desire to avoid pregnancy opted not to utilize any form of contraception during their most recent sexual activity

(Statistics Canada, n.d.). This highlights the underutilization of contraception options and emphasizes the pressing need for increased access and awareness.

A national survey published in the Journal of Obstetrician and Gynecology of Canada unveiled that women's contraceptive preferences differ, with approximately half opting for condoms, while 15% choose not to use contraception at all (Black et al., 2015). These findings highlight the necessity of promoting education and availability of oral contraceptives as a widely preferred method.

Despite Canada's renowned universal healthcare system and the importance placed on offering publicly funded services (Flood et al., 2000), disparities in medication coverage persist due to provincial government regulations governing drug coverage. Unintended pregnancies are expensive and can be burdensome for the Canadian health system. Annually, the number of unintended pregnancies in Canada is around 187,000 with an associated cost of over 320 million dollars. A study showed that 82% of this cost, amounting to $143 million, was associated with the lack of contraceptive use and improper use of contraceptives (Black et al., 2015). Because of the number of unintended pregnancies, more than 100,000 abortions take place each year and Canada (CIHI, n.d.) and one in three Canadian women will have an abortion during their reproductive lives (Norman et al., 2016). Emergency contraception in all of its forms is nearly always cost-effective for the healthcare system. The use of the drug reduces the cost of medical care by preventing unintended pregnancy (Foster et al., 2009).

Research findings indicate that expanding the accessibility of progestin-only ECPs does not lead to an increase in risk-taking behaviour, nor does it negatively impact ongoing contraceptive use. One study revealed that providing access to emergency contraception did not result in an increase in sexual activity among young adolescents. (Harper et al., 2005). Furthermore, a study illustrated that the utilization of emergency contraception not only increased awareness but also enhanced understanding of the medication (Williams et al., 2021).

Emergency contraception in Canada

In Canada, multiple modalities of emergency contraception are available. This includes the Yuzpe method, copper-T IUDs, progestin-only EC, and UPA. However, consistent with the rest of the world, the most widely used form of EC are the progestin-only ECPs. In Canada, progestin-only EC is available under various brand names such as Plan B®, NorLevo®, Next Choice®, and Take Action®. Across most provinces, these progestin-only ECPs can be acquired at local drugstores without a prescription or a pharmacy consultation and age, gender, or marital status restrictions. This streamlined access to a time-sensitive medication reduced barriers to service delivery. All of the other forms of EC available in Canada require a prescription and, in the case of the copper-T IUD, a consultation with a clinician. However, the deregulation of progestin-only EC sparked political controversies; some argued that emergency contraception was an abortifacient (Foster & Wynn, 2012) and others insisted that consultation with a healthcare professional was required for safe and effective use (Erdman, 2012).

Physicians and nurse practitioners are the primary prescribers of Schedule I drugs in the Canadian health system. In the case of drugs categorized as Schedule II, pharmacists gain the authority to prescribe them. Since 2008, progestin-only EC has been a Schedule III drug, meaning that, at least theoretically, the pills are available OTC. However, regulatory agencies in Quebec and Saskatchewan still treat progestin-only EC as a Schedule II drug and thus require a consultation with a pharmacist.

Despite widespread availability, barriers persist in obtaining prompt access to progestin-only EC. Studies and reports indicate that EC can be costly and challenging to obtain (Chaumont & Foster, 2016). Studies have repeatedly shown that progestin-only ECPs are often kept behind-the-counter, which effectively requires those seeking EC to consult a pharmacist. In rural areas of Ontario, limited hours of operation, especially on Sundays, pose additional barriers to access (Dunn et al., 2008). Although pharmacists are more accessible than other

health care providers, requiring a consultation to obtain EC can be intimidating and may result in delays in use.

Research in Canada also shows that there is a notable lack of awareness among the general public regarding ECPs, as well as other forms of contraception, making women less likely to utilize them (Munro et al., 2023). Some research indicates that Canadian women continue to mistakenly believe that emergency contraception in general, and progestin-only ECPs in particular, cause an abortion (Wynn et al., 2010). Further, because progestin-only ECPs are colloquially referred to as the "morning-after pill," there is persistent confusion over the timeframe (Wynn et al., 2010) and a lack of knowledge that ECPs can be used for up to 120 hours (five days) after intercourse (WHO, 2021). Proper education on EC is crucial to dispel misconceptions and promote correct medication usage.

Medication abortion in Canada

Although mifepristone is not available for use as an emergency contraceptive in Canada, mifepristone is available, with misoprostol, for use in medication abortion. Over 60 countries worldwide have approved this regimen for terminating early pregnancies. In recent years, interventions in the Global South have focused on increasing access to medication abortion drugs outside of the formal health system. These demedicalized strategies have often been employed out of necessity, in countries or contexts where abortion is severely legally restricted and/or safe and affordable abortion care is inaccessible. A body of research shows that misoprostol, with or without mifepristone, can be a safe and effective method for terminating a pregnancy outside of the formal health system (Moseson et al., 2020).

In 2015, Health Canada approved Mifegymiso®, a combined package comprising one 200mg tablet of mifepristone and four 200 mcg tablets of misoprostol. However, when first introduced in January 2017, access to Mifegymiso® was impeded by non-evidence-based requirements, necessitating out-of-pocket payments by pregnant individuals. Over subsequent

years, regulatory changes, including an extension of the gestational age limit, elimination of the physician dispensing requirement, and removal of the provider certification and ultrasound requirements, have significantly improved the accessibility of medication abortion, making it more widely available and easing financial barriers (Government of Canada, 2019a; 2019b).

Canada's regulatory environment combined with the fact that abortion is decriminalized and medication abortion is covered through insurance systems creates an opportunity for mifepristone to become a more accessible, available, and patient-friendly reproductive health option in the Canadian healthcare system. However, despite a favourable regulatory environment for medication abortion in Canada, persistent barriers hinder access to abortion services (Sabourin & Burnett, 2012). While the Canada Health Act mandates coverage for medically necessary procedures like abortion, the lack of universal drug coverage initially left Mifegymiso® uncovered by provincial and territorial insurance plans, imposing financial burdens on patients (LaRoche & Foster, 2020; Smith, 2020).

Identifying ways to expand access to abortion care, and medication abortion care in particular, have long been priorities within the reproductive health, rights, and justice community in Canada. Exploring ways to demedicalize medication abortion, create innovative service delivery strategies, and task shift provision within the health care team could make medication abortion care more accessible. However, deregulation of Mifegymiso® would be required for these types of changes to occur.

Rationale

This project investigates the deregulation of progestin-only emergency contraception in Canada and assesses the current availability of both progestin-only ECPs and UPA in Greater Ottawa. By conducting a scoping review of the deregulation journey, the study provides insights into the decision-making process and the levers and evidence marshalled to facilitate regulatory reform. Through a mystery client assessment of the current availability of ECPs in Greater

Ottawa, this project explores gaps in regulatory implementation. Overall, this research has the potential to enhance awareness of the availability and accessibility of EC in Canada and provide lessons on how sexual and reproductive health drug deregulation occurs.

Research questions and objectives

This multi-methods study set out to address four primary research questions:

1) What do we know about the regulatory journey of progestin-only emergency contraception in Canada?
2) What is the current availability and accessibility of ECPs in Greater Ottawa?
3) How can access to both progestin-only ECPs and UPA be improved?
4) What lessons can be drawn about the deregulation of reproductive health drugs from the regulatory journey of progestin-only ECPs?

The multi-methods design of the project combined with our partnership with the American Society for Emergency Contraception (ASEC) in fielding the mystery client study allowed us to address the following objectives: 1) Explore the regulatory reform journey of progestin-only emergency contraception in Canada; 2) Investigate the availability and accessibility of ECPs in Greater Ottawa; 3) Identify ways for EC service delivery and information about availability to be improved; and 4) Place the experience of EC in Canada in conversation with other reproductive health drugs and the availability of progestin-only EC in the United States.

Outline of thesis

This “thesis by articles” is divided into five chapters. The first chapter provides an overview of emergency contraceptive methods, contextual information about emergency contraception globally and in Canada, the project rationale, and the research questions and objectives. The second chapter describes the methodology used to respond to the research

questions and objectives. The third chapter contains an article entitled, “The regulatory journey of progestin-only emergency contraceptive pills in Canada: A scoping review.” This article has been formatted for and submitted to the *Canadian Journal of Human Sexuality*. The fourth chapter contains a report entitled, “Evaluating the availability and accessibility of emergency contraceptive pills in Greater Ottawa: Results from a mystery client study.” This report has been formatted per the requirements of ASEC, as this is part of a larger comparative project exploring the availability of progestin-only ECPs in both Canada and the United States. The final chapter begins by integrating the findings of the article and the report. This is followed by a discussion of future directions for increasing the availability and accessibility of ECPs in Canada and how the learnings from the progestin-only ECP story might inform the deregulation of other sexual and reproductive health drugs. I include a section on positionality and reflexivity and a statement of contribution before discussing the limitations of the project. The brief conclusion is followed by the reference list.

Chapter 2: Methods

Considering the nature of this project and after consultation with my supervisor, Dr. Angel M. Foster, we determined that a multi-methods qualitative study would be the most suitable approach to address the research questions. Qualitative data collection allows for researchers to gain a profound understanding of complex social and political issues within a healthcare system, especially in poorly researched areas (Sofaer, 1999). Consequently, we employed several data collection techniques throughout this thesis project. In this chapter, I detailed the methods used for the two study components, the scoping review and the mystery client study in Greater Ottawa. I also discuss the concept of triangulation and how the learnings from this project derive from considering the two study components in relationship to each other. I conclude with an exploration of the conceptual framework that undergirds the project and overarching ethical considerations.

Component I: Scoping review

To gain information on the regulatory journey of progestin-only ECPs in Canada, we conducted a scoping review. A scoping review allows researchers to explore a broad question and engage with a range of literature (Arksey & O'Malley, 2005; Munn et al., 2018). This type of review does not aim to synthesize results to answer a narrow question; rather, our purpose was to provide an overview of what is known about the progestin-only ECP regulatory process in Canada, identify gaps in the literature, recommend future research directions, and develop learnings that might inform deregulation of other sexual and reproductive health drugs. Prior to undertaking the scoping review, we conducted a cursory literature review and searched for any review protocols related to the regulation/deregulation of emergency contraception in Canada; our results highlighted that this issue has been underexplored.

For this scoping review, we employed the framework developed by Arksey and O'Malley (2005), which was later revised by Levac, Colquhoun, and O'Brien (2010). We followed the five-

step framework outlined by Levac and colleagues: identifying the research question, identifying relevant studies, selecting relevant studies based on defined criteria, charting the data, and subsequently collating, summarizing, and reporting our findings. Given the duration of time that had elapsed since the deregulation of progestin-only ECPs in Canada and the strength of the findings from the literature, we decided not to formally consult with topic experts, which is the sixth and optional step in the framework (Levac et al 2010). However, through presentations at conferences and meetings, we received informal feedback on the findings that informed our discussion and recommendations.

Identifying the research question

We undertook this scoping review to gain insight into what information about the regulatory history of progestin-only ECPs in Canada exists, with a focus on understanding processes of and advocacy surrounding deregulation. The primary research question that guided our scoping review was: *What do we know about the regulatory journey of progestin-only ECPs in Canada?*

Identifying relevant studies

To identify relevant articles, we searched multiple databases, including Medline/Embase, CINHAL, Scopus, ProQuest, AHMED, and Lexis Nexis, for published studies and abstracts. We selected these databases based on the interdisciplinary nature of the question and our desire to engage with a variety of source materials. We established inclusion and exclusion criteria for articles, grey literature, legislative documents, and media accounts. Our inclusion criteria encompassed resources discussing the regulatory changes, updates, and discussions regarding progestin-only ECPs in Canada. We also incorporated studies, reports, and articles that reported on the statements of healthcare providers and decision-makers related to the regulatory changes.

Selecting relevant studies

The selection process comprised two phases, the first of which involved reviewing titles and abstracts for inclusion based on specified criteria. Sources lacking abstracts were automatically moved to the second phase, where we assessed full texts for eligibility and conducted hand-searching of reference lists. We used Covidence (2022) to streamline screening and manage duplicates.

Charting the data

The study utilized Microsoft Excel® to systematically record and refine key information from various sources, adjusting and updating the data iteratively during the extraction process. Following Levac et al.'s (2010) three-step analysis approach, the study provided a descriptive summary highlighting source characteristic, identified key themes, and organized studies based on jurisdictional focus and regulatory stage for a comprehensive understanding.

Collating, summarizing, and reporting the findings

This scoping review analyzed 46 sources, including 16 peer-reviewed journal articles, scholarly books, or abstracts, 21 medical news articles, 3 government documents, 2 clinical practice guidelines, and 4 other publications. Notably, there were no systematic or scoping reviews specifically addressing the regulatory status of progestin-only emergency contraception. Spanning the years 1999 to 2020, with one source predating 2000 and three postdating 2017, the majority of articles (29 out of 46) focused on the availability of emergency contraception in the behind-the-counter era. While the research question centered on Canada, the source material predominantly originated from British Colombia, Ontario, Quebec, and Saskatchewan, with limited representation from other provinces and none from the territories. We meticulously charted relevant information and conducted thematic analyses to ensure an accurate report of

the literature. To guide the reporting process, we utilized the PRISMA extension for scoping reviews (Prisma-ScR) checklist by Tricco et al. (2018). We also modelled our report after other scoping reviews produced by Dr. Foster's research group (Demont et al., 2023; Dixit et al under review). The ultimate reporting output of the scoping review is the article presented in Chapter 3.

<u>Component II: A mystery client study of the availability and accessibility of EC in pharmacies in Greater Ottawa</u>

Building on the previous work of Dr. Foster's research group (Borsella & Foster, 2021.; Chaumont & Foster, 2017; Foster et al., 2017; Cleland et al, 2016), we conducted a mystery client study to understand the real-life availability and accessibility of ECPs in Greater Ontario. Although this component of the study emphasized the availability and accessibility of progestin-only ECPs, we also explored the status of UPA in pharmacies in Greater Ontario. We conducted this component of the project in partnership with ASEC.

Partner description: The American Society of Emergency Contraception

The American Society for Emergency Contraception is dedicated to fostering safe access to emergency contraception, with a focus on minimizing barriers and reducing stigma. ASEC serves as a dependable source of information on emergency contraception in the United States, contributing to the broader landscape of reproductive health, rights, and justice. ASEC's mission includes offering expert guidance, organizing an annual meeting dedicated to emergency contraception, disseminating information, and leading nationwide campaigns such as "Emergency Contraception for Every Campus."(*About | American Society for Emergency Contraception*, n.d.). ASEC also conducts research to assess the availability and accessibility of emergency contraception.

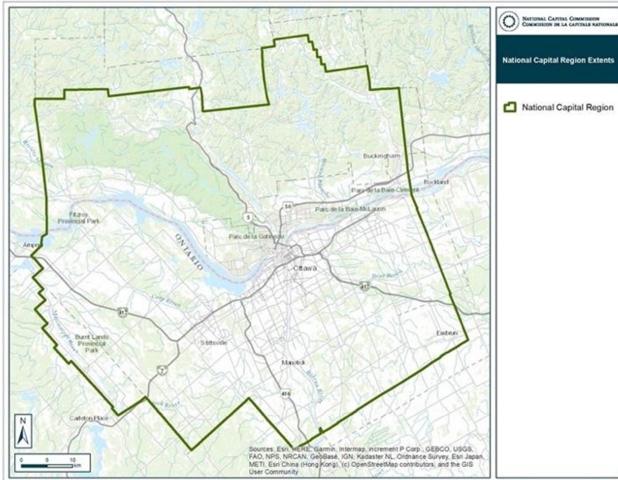
Study design

In 2016, the American Society of Emergency Contraception conducted a mystery client study, investigating the accessibility of progestin-only ECPs in the United States (Cleland et al., 2016). In 2022, seeking to replicate the 2016 study, ASEC provided volunteers with a questionnaire to visit local pharmacies. These volunteers collected information and made inquiries about progestin-only ECPs and UPA from pharmacy staff. The questionnaire, distributed through a link, seamlessly generated responses upon completion, ensuring efficient data access and producing clear results.

The project aimed to update crowdsourced knowledge of the availability and accessibility of progestin-only ECPs in the US and explore the availability and accessibility of UPA; although UPA remains a prescription-only drug in the US, ASEC had an interest in understanding whether information about UPA was available to EC seekers. For comparative reasons, ASEC also wanted to expand their project to include Canada; ASEC partnered with Dr. Foster's research team on this endeavor. As Study Coordinator, I led the mystery client study in Canada and focused on the availability and accessibility of EC in Greater Ottawa.

Study area

The Greater Ottawa region is renowned for its rich cultural heritage and historic landmarks. Situated in the eastern part of Ontario, it encompasses the city of Ottawa, also recognized as the national capital of Canada, along with surrounding communities across the Ottawa River in Gatineau, Quebec (see Fig. 1). Ottawa serves as the seat of the Canadian government and is located in the unceded and unsurrendered territory of the Anishinaabe Algonquin People.



<u>Figure 1: Map of the greater Ottawa Region (Harris, 2019)</u>

Despite the close geographic proximity, the regulatory status of progestin-only ECPs varies significantly in this region. In Ontario, these pills have been available over the counter without the need for a prescription or consultation since 2008 (Chaumont & Foster, 2017b; Eggertson, 2008). However, in the province of Quebec, access to progestin-only ECPs involves obtaining the medication after an encounter with a pharmacist who then prescribes the medication (Soper & Di Meglio, 2020; Éditeur officiel du Québec, 2011).

In collaboration with ASEC, we adapted their protocol for our study to account for the availability of progestin-only ECPs and included UPA, recognizing its presence in Canada since 2016. Drawing on the framework of previous mystery-client studies (Tavares & Foster, 2016; Borsella & Foster, 2020), our investigation unfolded over the summer of 2022 across the Greater Ottawa area. Volunteers, embodying the role of emergency contraception seekers, engaged in the task of obtaining progestin-only ECPs.

To ensure accessibility, our questionnaires were available in both English and French. Initially, volunteers focused on the location/placement of progestin-only ECPs, brands available, listed prices, and any security features impacting on-shelf availability. Volunteers then engaged with a pharmacy representative to explore product availability, service delivery, age restrictions,

and the possibility of men purchasing progestin-only ECPs. Additionally, we sought information on the cost and accessibility of UPA.

Recruiting volunteers from the university, we provided invitations, instructions, and support contact information. To facilitate the data collection process, we actively addressed all questions and issues, guiding volunteers throughout. Each volunteer spent approximately 15 minutes at their chosen pharmacy, and upon completing the survey, responses were recorded in a live spreadsheet on Google Docs.

Data collection

Data collection spanned from June to September 2022. Utilizing a database obtained in May 2022 from ASEC, we tracked pharmacy visits, sought additional input in areas with limited responses, and conducted additional surveys to achieve a substantial sample size. We completed a total of 124 surveys, covering 99 visited pharmacies; we used the pharmacy as the unit of analysis and assigned a numeric identifier. The survey, accessible through various devices or as a printable version, comprised two main parts. The first part involved observing stocked EC shelves, and addressing cost, accessibility challenges, and limitations. The second part required volunteers to pose questions to pharmacy staff, including about UPA's availability and cost. We entered volunteers into a draw for four $50 Amazon gift cards as a token of appreciation for their time.

Data analysis

Upon questionnaire submission, responses were automatically recorded in a spreadsheet. Data organization and coding occurred in Microsoft Excel®, involving descriptive statistics. Concurrently, field notes and comments underwent scrutiny, with memoing of content and identification of themes using deductive and inductive techniques. Data analysis focused on individual pharmacies as the unit of analysis. We combined information from multiple visits to

the same pharmacy for a comprehensive overview of availability, accessibility, location, and price.

Triangulation

Triangulation involves employing diverse methods to complement and intersect findings when examining a phenomenon (Natow, 2020; Thurmond, 2001). By employing two distinct study components to investigate regulatory changes, as well as the current availability and accessibility of emergency contraception, we aimed to illustrate the disparity between policy and practice. The two components exhibit coherence with each other, revealing consistent findings regarding the current availability (or lack thereof) and barriers to access. The presentation of these findings to ASEC members and other experts facilitated recommendations for future directions, which center on how to achieve greater concordance between regulatory status and clinical practice. Despite the regulatory status of progestin-only ECPs being clearly stated in legislation and clinical practice, our interactions with local pharmacists confirmed a lack of congruence in practices among pharmacists and pharmacy staff.

Conceptual framework

This thesis sought to explore regulatory reform and contemporary practices surrounding emergency contraception pills. The project aimed to delve into the implementation of policy examining policy as conceptualized in writing versus the lived experience of it. Our objective was to identify points of divergence (Rosaline, 2008) and identify avenues for better-aligning policy and practice. Thus, this project was conceptualized as action research to inform policies and service delivery.

Ethical considerations

After examining the criteria outlined in Article 2.1 of the Tri-Council Policy Statement, 2nd edition (Government of Canada, 2022), the Office of Research Ethics and Integrity at the University of Ottawa has determined that mystery client studies involving pharmacies do not necessitate REB (Research Ethics Board) review. This determination is rooted in the nature of these studies, which primarily assess professional practices and do not involve “human participants” as defined by this policy. In our study, we have carefully masked all identifiable information regarding individual pharmacies and their employees.

Chapter 3: Article #1

We submitted this article to the *Canadian Journal of Human Sexuality*. The article conforms to the structural, word count, and formatting requirements of this peer-reviewed journal.

The regulatory journey of progestin-only emergency contraceptive pills in Canada: A scoping review

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The regulatory journey of progestin-only emergency contraceptive pills in Canada: A scoping review

Abstract

Over the last three decades, the regulatory status of progestin-only emergency contraceptive pills in Canada changed from being a Schedule I (prescription-only) to a Schedule III (over-the-counter) drug. We undertook this scoping review to trace the regulatory journey of progestin-only emergency contraception and identify learnings that might apply to the deregulation of other reproductive health drugs. We used a five-stage established framework to guide this scoping review. After identifying a range of search terms, we searched for source material in the following databases: AMED (allied and complimentary medicine), Medline/Embase, CINAHL, PsycInfo, LexisNexis, Canadian Public Policy, Scopus, and Sociological Abstracts via ProQuest. We identified 46 relevant sources between the years 1995 and 2020 (inclusive). This body of literature sheds light on both the federal and provincial processes involved in drug deregulation in Canada, the importance of advocacy in supporting deregulation efforts, and the controversies and resistance that emerged due to the deregulation of progestin-only emergency contraceptive pills at both the national and provincial levels. We conclude with a discussion of what these findings might mean for ongoing efforts to deregulate other safe and effective reproductive health drugs, including ulipristal acetate and mifepristone, in Canada.

Keywords: Canada, deregulation, emergency contraception, levonorgestrel, medications, scoping review, sexual and reproductive health

Introduction

Emergency contraceptives are methods or devices that are used after sex to reduce the risk of pregnancy (World Health Organization (WHO), 2021) and offer an important tool in helping women and other pregnancy-capable people regulate their fertility and exercise reproductive autonomy (Erdman & Cook, 2016). Worldwide, progestin-only emergency contraceptive pills (ECPs) are the most common and well-known form of post-coital contraception. These pills contain 1.5mg of levonorgestrel and can be used up to 5 days after unprotected or under-protected sexual intercourse. However, progestin-only ECPs are most effective when taken immediately after sex (Trussell, 2012) and thus timely access is critical.

Prior to 1969, contraceptive methods (which at the time included a limited range of barrier methods and oral contraceptive pills), could only officially be prescribed for reasons unrelated to pregnancy prevention in Canada. However, after decades of advocacy and mobilization the Canadian federal government passed Bill C-150 that removed contraception from the criminal code (Ederman, 2012). In the 1970s, a Canadian physician, Albert Yuzpe, began prescribing combined oral contraceptive pills for post-coital use (Foster & Wynn, 2012). This off-label use of daily oral contraceptive pills set the stage for the development of dedicated ECPs, that is pills that are labeled, dosed, marketed, and sold specifically for use after sex.

Health Canada, the federal government agency responsible for Canadian health policy, first approved a dedicated progestin-only ECP under the brand name PlanB® in 2000. Post-coital use of progestin-only pills had considerable benefits over the use of combined oral contraceptive pills after sex, as they were more effective and had fewer side effects (Trussell, 2012). As is the case with most drugs, Health Canada's original approval classified progestin-only ECPs as a Schedule I drug, meaning that a clinician had to prescribe the drug for a patient to obtain it at a

pharmacy. Over the subsequent decade, the regulatory status of this drug evolved, first to Schedule II (behind-the-counter) status in 2005 and then to over-the-counter status as a Schedule III drug in 2008 (Eggertson, 2008). The National Association of Pharmacy Regulatory Authorities (NAPRA) determines drug scheduling at the federal level, a process that creates the sale conditions attached to a particular drug and helps ensure that provincial regulations align with federal standards and with each other (Erdman & Cook, 2016). However, individual provinces also moved to change the regulatory status of progestin-only ECPs, including early efforts in British Columbia to allow pharmacist dispensing (NAPRA, 2017).

Although the stages in the regulatory journey of progestin-only ECPs have been well-documented and a body of research has focused on the availability of ECPs during these different phases, far less is known about the processes and advocacy that resulted in those regulatory changes. Understanding the regulatory reform process could shed light on how other reproductive health drugs could be deregulated in Canada, a process that has the potential to foster equitable and timely access to care. We undertook this scoping review to gain insight into what information about the regulatory history of progestin-only ECPs in Canada exists, with a focus on understanding the processes of and advocacy surrounding deregulation. The primary research question of our scoping review was: *What do we know about the regulatory journey of progestin-only emergency contraceptive pills in Canada?*

Methods

We developed a protocol using the scoping review framework published by Arksey and O'Mally (2005) and revised by Levac and colleagues (2010). This five-step process involved identifying our research question followed by identifying relevant studies, selecting literature based on our inclusion and exclusion criteria, charting data from the selected source material,

and ultimately collating, summarizing, and reporting our data. We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist to ensure compliance with reporting standards (Page et al., 2021; Tricco et al., 2018). We decided not to undertake the optional sixth step of the framework, which involves expert consultation, because of the clarity and strength of the findings obtained from engaging with the literature.

Eligibility criteria and data sources

We began the scoping review process by developing a formal protocol; EF drafted the protocol and AD and AMF provided input. In order to cast a wide net, we decided to include all types of articles that described the regulatory status of progestin-only ECPs in Canada, including primary research studies, legal and policy reviews, guidelines, reports, books and book chapters, abstracts, and reports from conference proceedings. We did not impose any specific exclusion criteria based on the type of source or study design. We included studies that focused on any allied health care professional group or patients if the material discussed regulatory reform or regulatory changes. We included items published in French or English that focused on Canada at the federal, provincial, or territorial level. We temporally bounded our study by only including sources published from 1995 to 2020, as this allowed us to go into depth regarding the full regulatory journey of progestin-only ECPs in Canada. We excluded items if they focused on non-regulatory barriers to accessibility, use or acceptability of progestin-only ECPs, other modalities of ECPs (including the Yuzpe method and ulipristal acetate), and/or (medication) abortion, as these topics are outside of the scope of this review. We present these criteria in Table 1.

[Table 1 about here]

Search strategy

To identify studies, media articles, and government documents, we conducted searches using several key words/terms when searching in the databases. Although we adapted our search terms to each database, our general strategy included the following primary terms: emergency contracept*, levonorgestrel, post-coital contracept*, deregulat*, health policy, legislat*, access*, regulat*, government regulation, Canada (as well as all the provinces and territories). We used a range of search terms, alone and in combination, that allowed us to capture a wide range of information. We provide an example of the search strategy in Table 2. To increase the search sensitivity, we did not apply any language restrictions but did include the date range (1995-2020) outlined in our inclusion/exclusion criteria. We used multiple databases including AMED (allied and complimentary medicine), Medline/Embase, CINAHL, PsycInfo, LexisNexis, Canadian Public Policy, Scopus, and Sociological Abstracts via ProQuest as this allowed us to engage with a broader array of information reflecting different disciplinary thinking.

[Table 2 about here]

We also conducted a "hand search" of the reference lists of all eligible sources from our database searches. In addition, we searched grey literature, including government agencies' reports and news articles. We used Google as the principal search engine and reviewed the first 100 unique sources that the platform determined as most relevant.

To develop our search terms, we first conferred as a study team and then we consulted with both a health sciences librarian and a law librarian at the University of Ottawa. To help identify and organize the results, we used Microsoft Excel® to capture basic information about which strategy (database, hand search, Google), specific database (if applicable), and specific search term(s) allowed us to identify the source material.

Study selection

Our screening process consisted of two phases. In the first phase, EF reviewed the title and abstract for inclusion based on our criteria; she automatically moved any source that did not have an abstract to the phase two screen. In the second phase, EF reviewed the full text to determine the eligibility of the source. In this phase, she hand-searched the reference lists to identify additional materials. To simplify this process, EF utilized Covidence (2022), an online systematic review software, to organize the screening process and remove duplicates. AD and AMF were available to discuss complicated or ambiguous sources.

Data extraction and synthesis of results

We used Microsoft Excel® to record key information from each eligible source including aims of the study, regulatory status phase, geographic area, studied population(s), and key findings. We adjusted or updated the information we collected iteratively as we worked through the extraction process and got more familiar with the study data.

Per Levac and colleagues (2010), we used a three-step process to analyze the data, report results, and apply meaning to sources we found. Our analysis included a descriptive summary that focused on the characteristics of included sources and a review of key themes. We

also grouped the studies by the jurisdictional focus (federal or specific province/territory) and regulatory stage.

Results

PRISMA outline

Our search strategy yielded a total of 138 sources from the scientific databases. After eliminating duplicates (n=54), we screened 94 sources retrieved from the scientific databases for title and abstract and then reviewed the full texts of 37 pieces of literature; 30 of those ultimately met our inclusion criteria and are included in this review. We also identified 70 sources through Google (n=38), hand searches (n=29), websites (n=2), and organizations (n=1). Based on our review we excluded 54 sources because they were duplicates (n=32) or irrelevant (n=22). Ultimately, we included 46 sources in our final analysis (see Fig 1.).

[Figure 1 about here]

Characteristics of literature

Of the 46 sources we included in this review, 16 were peer-reviewed journal articles, scholarly books, or abstracts, 21 were medical news articles, 3 were government documents, 2 were clinical practice guidelines, and 4 were other types of publications. We found no systematic or scoping reviews that focused on the regulatory status of progestin-only ECPs. All sources were published between 1999 and 2020; only one was published before 2000 and only three were published after 2017. Most of the published articles focused on the availability of emergency contraception behind-the-counter (n=29). While our research primarily concentrated

on Canada, province-specific source material largely centered on British Columbia and Ontario. We found few studies from other provinces and none of the source material focused on the territories. We present information about these characteristics on Table 3.

[Table 3 about here]

Findings from the synthesis

We begin the presentation of our findings with some of the overarching themes we identified in the source material. We summarize some of the key findings from the 16 peer-reviewed journal articles, scholarly books, or abstracts in Table 4. We then organize our findings from the review and the narrative synthesis around the different phases of the regulatory journey of progestin-only EC: approval and introduction as a prescription-only medication, transition to behind-the-counter status, and deregulation to over-the-counter status.

[Table 4 about here]

Much of the original research that touches on the regulatory journey of progestin-only EC in Canada centers on the knowledge and practices of clinicians (SOGC, 2003; Dunn et al, 2003a; Langille et al., 2012; Leung et al., 2008) and pharmacists (Chaumont & Foster, 2017; Cohen et al., 2004; Wynn et al., 2007; Eggertson & Sibbald, 2005), as well as the knowledge and experiences of patients (Shoveller et al., 2007; Hukku et al., 2018). Articles that explored the availability of progestin-only EC in pharmacies (Dunn et al., 2003b; Dunn et al., 2008; Chaumont & Foster, 2017; Borsella & Foster, 2020) often frame that work around compliance

with the shifting regulatory status of the drug. Other articles explicitly examined the regulatory changes in the status of progestin-only ECPs and the implications for access (CWHN, 2005; Pancham & Dunn, 2007; Schiappacasse & Diaz, 2006). Finally, a small body of research focused on the regulatory history of progestin-only ECPs in British Columbia that includes results from early initiatives to allow pharmacists to dispense the medication (Soon et al, 2002; Soon et al, 2004; Soon et al 2005; (B.C. Reg.417, 2009). While the main intent of these articles is to present research and program evaluation findings, they all contextualize their studies by presenting arguments supporting the necessity or advantages of deregulating progestin-only ECPs.

The approval and introduction of progestin-only ECPs: Schedule I status

Progestin-only ECPs were initially classified as a Schedule I drug and patients were required to obtain a prescription from a physician (NAPRA, 2017). Literature from this era showcases that accessing progestin-only ECPs during this period was difficult due to the lack of physician availability and limited clinic operating hours (Cohen et al., 2004). Further, misinformation among physicians about progestin-only ECPs (Dunn et al., 2003a) and fear of provider judgment and discrimination (Dunn, 2001) created further barriers to timely access. Advocates and medical journalists began calling for progestin-only ECPs to be made available directly from pharmacies to increase timely access to the drug, framing this as an important strategy for reducing unintended pregnancy at the population level (Eggertson, 2006a; Black et al., 2016).

Pilot studies implemented during this period highlighted the public demand for pharmacy access (Osmond, 2000; Rhyno, 2001b). Importantly, in the wake of Health Canada’s approval of progestin-only ECPs, healthcare providers in British Columbia launched a pilot program that

allowed pharmacists to dispense progestin-only ECPs through a prescribing agreement after conducting an intake assessment (Sibbald, 2000; Soon et al., 2002). A number of articles published in this early phase of the regulatory journey of progestin-only ECPs focus on this pilot and establish the evidence-base for a switch to Schedule II status at the federal level (Leung et al., 2008; Soon et al., 2005). Other provinces soon followed suit, including Quebec (Dunn et al, 2003a) and Saskatchewan (Rhyno, 2000b; Sibbald, 1999; Soon et al., 2004). Marshalling this evidence, building the case for the regulatory change, and engaging with national regulatory authorities are central goals of the articles that focus on this period (Eggertson, 2006a, 2006b; Sibbald, 1999, 2001, 2005; Kermode-Scott, 2008; Osmond, 2000).

The transition to behind-the-counter: Schedule II status

In the late 1990s and early 2000s many organizations including the Society of Obstetricians and Gynecologists of Canada (SOCG), National Drug Scheduling Advisory Committee (NDSAC), NAPRA, Canadian Nurses Association (CNA), Royal College of Physicians and Surgeons of Canada (RCPS), Federation of Medical Women of Canada (FMWC), and Canadian Pediatric Society (CPS) collectively supported making progestin-only ECPs available behind-the-counter (Sibbald, 1999; Soon et al., 2004; Government of Canada, 2004; Business Wire, 2002; Business Wire, 1997). Evidence that the prescription-only status of progestin-only ECPs delayed access to a time-sensitive medication proved to be compelling (Dunn, 2001). Health Canada met with five organizations that promoted regulatory reform and ultimately decided to support the move to Schedule II status (Sibbald, 2001; Ederman, 2012).

Stakeholder engagement appears to have been critical; over 300 stakeholders advocated for deregulation of progestin-only ECPs (Rhyno, 2001a). The manufacturer of Plan B®, Paladin

Labs, applied for the change in status and in doing so became the first company to request this regulatory change at the federal level. The director of the Canadian Pharmacists Association (CPhA) advocated training pharmacists to dispense progestin-only ECPs (Nguyen, 2005); the transition to Schedule II status was also intertwined with a broader effort within the pharmacy community to gain recognition of their essential role as health service providers who should be compensated accordingly (Lynas, 2005; Government of Canada, 2004a). Thus, deregulation to Schedule II status was heavily influenced by evidence that documented feasibility and need, the advocacy efforts of both professional and reproductive health associations, and the mobilization of pharmacist associations (Sibbald, 2005). Health Canada approved the shift to Schedule II status in April 2005.

Deregulation to become over-the-counter: Schedule III status

Initially, the regulatory shift from prescription to behind-the-counter status was lauded for showcasing the professionalism of pharmacists and the alignment of progestin-only ECP prescribing and their scope of practice (McCutcheon et al, 2005; Osmond, 2000; Dunn et al., 2008, CMAJ, 2005). Deregulation from Schedule I to Schedule II status also highlighted the compensation inequality between pharmacists and physicians and prompted important discussions about the role of the healthcare team in providing sexual and reproductive health services (Ederman, 2012; Wynn et al., 2007; Eggerton and Sibbald, 2005; Murray, 2006).

However, this enthusiasm appears to have been short-lived. Evidence on the global level demonstrated that progestin-only ECPs were extremely safe that there were no risks that outweighed the benefits of use (Foster & Wynn, 2012), that side effects were minimal and transient (Cook et al., 2006), and that there were no contraindications to use (Erdman & Cook,

2006; Leung et al., 2008). This prompted questions about why obtaining progestin-only ECPs required any type of consultation with a healthcare professional. Indeed, evidence soon emerged that requiring a consultation with a pharmacist created barriers to timely access, forced patients to incur unnecessary costs, and exposed patients to discrimination and belief-based denial of care and referrals (Erdman & Cook, 2006; CWHN, 2005; Murray, 2006; Eggertson 2006a; Eggertson 2006b; Marketwire, 2008; Lynd et al., 2005). In response, the Canadian Women's Health Network and SOGC submitted a public interest petition to NAPRA advocating for progestin-only ECPs to be moved to Schedule III (over-the-counter) status, an effort that was officially supported by Paladin Labs in 2007 (Kermode-Scott, 2008).

However, despite its former alliance with the SOGC, the CPhA opposed this change in status (Ederman, 2012). Thus, the final stage in the deregulation journey of progestin-only ECPs reflects a division among advocates. This dissent reflected broader issues related to the role and compensation of pharmacists within the Canadian health care system but was often cloaked in discussions about how consultations were necessary to ensure appropriate use (Wynn et al., 2007). Advocates were quick to point out that overregulation of progestin-only ECPs not only reflected non-evidence-based healthcare policies but denied women a basic human right to reproductive autonomy (Erdman & Cook, 2006; Cook et al., 2006). Although the official switch to Schedule III status occurred in 2008, both Quebec and Saskatchewan continued to require that women seeking progestin-only EC consult with a pharmacist. Research in multiple provinces after official deregulation showed that despite the regulatory shift, many pharmacies continued to carry progestin-only ECPs behind-the-counter (Yuksel et al., 2011; Hukku et al., 2018).

Discussion

The findings of our scoping review suggest that evidence was critical to the deregulation of progestin-only ECPs in Canada (Dunn, 2001; Kermode-Scott, 2008; Marketwire, 2008; NAPRA, 2017; Schiappacasse & Diaz, 2006). However, identifying ways to marshal that evidence was equally important. Mobilized and coordinated actions, including lobbying, writing letters, and submitting petitions led to the deregulation of progestin-only ECPs (Soon et al.,2004; Government of Canada, 2004b; Business Wire, 2002; Business Wire,1997). The existing literature highlights the importance of knowledge mobilization and translation in supporting regulatory reform.

The regulatory journey of progestin-only ECPs also demonstrates the power of pilot initiatives to shape decision-making. Early efforts in British Columbia to show the feasibility of pharmacy access played a key role in convincing federal regulators to reclassify progestin-only ECPs (CMAJ, 2005; Sibbald, 2000; Shoveller et al., 2007; Soon et al., 2005). Thus, one of the lessons from the story of progestin-only ECPs in Canada is how important it is to both take advantage of opportunities to engage in innovative service delivery strategies and rigorously document the outcomes of those efforts.

The journey of progestin-only ECPs also showcases the importance of professional associations and colleges in both advocating for and resisting regulatory reform (Eggertson 2006b; Lynas, 2005; Nguyen, 2005; Pancham & Dunn, 2007; Soon et al., 2002). Inter-sectoral partners in the early 2000s supported the move to Schedule II status; divisions among professional groups created barriers to the transition to Schedule III status (Yuksel et al., 2011). Future efforts to deregulate reproductive health drugs would benefit from considering these dynamics and identifying and cultivating champions within all relevant professional groups.

Finally, a critical element of the deregulation story was the continuously and consistently documented unmet need for timely, non-judgmental, and affordable access to progestin-only ECPs (Black et al., 2016; Langille et al., 2012; Leung et al., 2008). Studies documenting how the regulatory status of progestin-only ECPs created barriers to access and timely use – and studies showing that feasible strategies could reduce or eliminate those barriers – became an important tool for advocates. The decisions by federal agencies to support deregulation also repeatedly cited the needs of women seeking a post-coital method of pregnancy prevention. This is a reminder of the importance of documenting the experiences of those directly impacted by policies and lifting patient voices.

These lessons may prove valuable for supporting the deregulation of other safe and effective reproductive health drugs in Canada. Ulipristal acetate is a second-generation dedicated ECP that is more effective than progestin-only ECPs, especially from hours 73-120 and when taken by patients who are over 165 pounds (Trussell 2012; WHO 2021). Although ulipristal acetate is available over-the-counter in more than a dozen countries and has been deregulated by the European Medicines Agency, this medication still requires a prescription in Canada. Mifepristone, the first drug in the gold standard medication abortion regimen, is also a Schedule I drug in Canada despite global evidence that it can be used safely and effectively through a range of health service providers and service delivery strategies. Using the regulatory journey of progestin-only ECPs as a guide and recognizing the importance of engaging in knowledge translation and mobilization efforts, conducting and evaluating pilot interventions, and capturing the lived experiences of those who need services, could help the reproductive health, rights, and justice community develop a multi-pronged strategy for deregulating these other important

medications.

Limitations

Although we attempted to use a full range of search terms, we recognize we might not have obtained all relevant source material, particularly sources that are not indexed in scientific databases. Our scoping review focused exclusively on progestin-only ECPs; exploring the history and deregulation of all contraceptives in Canada could have opened more areas of inquiry. We also did not carry out a critical appraisal of individual sources because we did not want to exclude learnings from any source due to quality.

Conclusion

Our scoping review provides insight into the regulatory journey of progestin-only ECPs in Canada. The published literature shows that rigorous research, evidence-based advocacy, professional association mobilization, and the experiences of patients all played a role in moving the drug from prescription to over-the-counter status in less than a decade. The learnings from the deregulation of progestin-only ECPs can inform the work of researchers, health service providers, and advocates working to deregulate and demedicalize other reproductive health technologies in Canada.

References

Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology*, *8*(1), 19–32.

B.C. Reg.417. (2009). *Pharmacists Regulation*. https://www.bclaws.gov.bc.ca/civix/document/id/loo87/loo87/28_417_2008

Black, A., Guilbert, E., Costescu, D., Dunn, S., Fisher, W., Kives, S., Mirosh, M., Norman, W., Pymar, H., Reid, R., Roy, G., Varto, H., Waddington, A., Wagner, M.-S., & Whelan, A. M. (2016). Canadian Contraception Consensus (Part 3 of 4): Chapter 8 – Progestin-only contraception. *Journal of Obstetrics and Gynaecology Canada*, 38(3), 279–300. https://doi.org/10.1016/j.jogc.2015.12.003

Borsella, M., & Foster, A. M. (2020). Exploring the availability of emergency contraception in New Brunswick pharmacies: A mystery-client telephone study. *Pharmacy*, *8*(2), 76.

Business Wire (2002, March 8). Application to take Plan B emergency contraception over-the-counter submitted in Canada. *Business Wire*, 1.

Business Wire (1997). Obstetricians recommend morning-after pill. *Canadian Press Enterprises Inc.*

Chaumont, A., & Foster, A. M. (2017). The not so over-the-counter status of emergency contraception in Ontario: A mixed methods study with pharmacists. *FACETS*, 2(1), 429–439.

CMAJ. (2005). Emergency contraception moves behind the counter. *Canadian Medical Association. Journal: CMAJ*, 172(7), 845, 847.

Cohen, M. M., Dunn, S., Cockerill, R., & Brown, T. E. (2004). Using a secret shopper to evaluate pharmacist provision of emergency contraception: Satisfaction levels high, with privacy a concern. *Canadian Pharmacists Journal,* 137(1), 28–33.

Cook, R., Dickens, B., & Erdman, J. N. (2006). *Emergency contraception, abortion and evidence-based law*. file:///Users/emiliefriesen/Downloads/SSRN-id944810_stamped%20(1).pdf

Covidence. (2022). *Covidence systematic review software.* Melbourne, Australia. Veritas health innovation. Available at www.covidence.org.

CWHN. (2005). *Improving access to emergency contraception*. https://books-scholarsportal-info.proxy.bib.uottawa.ca/en/read?id=/ebooks/ebooks0/gibson_cppc/2009-12-01/3/203273#page=1

Dunn, S., Brown, T. E., & Alldred, J. (2008). Availability of emergency contraception after its deregulation from prescription-only status: A survey of Ontario pharmacies. *Canadian Medical Association. Journal: CMAJ*, *178*(4), 423–424.

Dunn, S., Guilbert, E., Lefebvre, G., Allaire, C., Arneja, J., Birch, C., Fortier, M., Jeffrey, J., Vilos, G., Wagner, M. S., Grant, L., Beaudoin, F., Cherniak, D., Pellizzari, R., Sadownik, L., Saraf-Dhar, R., Turnbull, V., & Clinical Practice Gyneacology and Social Sexual Issues Committees, Society of Obstetricians and Gyneacologists of Canada (SOGC) (2003a). Emergency contraception. *Journal of obstetrics and gynaecology Canada: JOGC*, 25(8), 673–690.

Dunn, S., Brown, T. E. R., Cohen, M. M., Cockerill, R., Wichman, K., Weir, N., & Pancham, A. (2003b). Pharmacy provision of emergency contraception: The Ontario emergency contraception pilot project. *Journal of Obstetrics and Gynaecology Canada: JOGC*, 25(11), 923–930. https://doi.org/10.1016/s1701-2163(16)30240-7

Ederman, J. N. (2012). *Canada: Competing frames of access and authority*. In *Emergency contraception: The story of a global reproductive health technology*, Foster, A. M., & Wynn, L. L. (Eds.). Palgrave Macmillan: New York; pp 57-78.

Erdman, & Cook, R. J. (2016). Protecting fairness in women's health: The case of emergency contraception. In *Just Medicare*. University of Toronto Press: Toronto; pp 137-167.

Eggertson, L. (2006a). *Manitoba pharmacists' association clarifies Plan B regulations*. *Canadian Medical Association. Journal: CMAJ.*

Eggertson, L. (2006b). *Ontario pharmacists drop Plan B screening form*. Can Med Assoc.

Eggertson, L. (2008). Plan B comes out from behind the counter. *CMAJ: Canadian Medical Association Journal = Journal de l'Association Medicale Canadienne,* 178(13), 1645–1646. https://doi.org/10.1503/cmaj.080809

Eggertson, L., & Sibbald, B. (2005). *Privacy issues raised over Plan B: Women asked for names, addresses, sexual history*. *Canadian Medical Association. Journal: CMAJ*

Foster, A. M., & Wynn, L. L. (Eds.). (2012). *Emergency contraception: The story of a global reproductive health technology*. Palgrave Macmillan: New York.

Government of Canada. (2004a). *Government of Canada*. Canada.ca. https://www.canada.ca/en/news/archive/2004/05/government-canada-proposes-access-morning-after-pill-without-prescription.html

Government of Canada. (2004b). Canada Gazette Part I. 138(21), 55.

Hukku, S., Gauthier-Beaupré, A., Fortier, E., Doci, F., Veillet-Lemay, G., Gure, F., LaRoche, K., & Foster, A. M. (2018). Exploring young adults' knowledge of and experiences with emergency contraception in Ontario, Canada: A mixed-methods study. *Contraception*, 98(4), 359.

Kermode-Scott, B. (2008). Canada's drug advisory committee says emergency contraception should be available over the counter. *British Medical Journal Publishing Group.*

Langille, D. B., Allen, M., & Whelan, A. M. (2012). Emergency contraception: Knowledge and attitudes of Nova Scotian family physicians. *Canadian Family Physician*, 58(5), 548–554.

Leung, V. W. Y., Soon, J. A., & Levine, M. (2008). Emergency contraception update: A Canadian perspective. *Clinical Pharmacology & Therapeutics*, 83(1), 177–180.

Levac, D., Colquhoun, H., & O'Brien, K. K. (2010). Scoping studies: Advancing the methodology. *Implementation Science*, 5(1), 69. https://doi.org/10.1186/1748-5908-5-69

Lynas, K. (2005). Pharmacists to provide ECP without doctor's prescription. *Canadian Pharmacists Journal*, 138(4), 13.

Lynd, L. D., Taylor, J., Dobson, R., & Willison, D. J. (2005). Prescription to over-the-counter deregulation in Canada: Are we ready for it, or do we need to be? *Canadian Medical Association. Journal: CMAJ*, 173(7), 775–777.

Marketwire. (2008). Pharmacists disappointed by emergency contraception decision. *Marketwire*. https://www.proquest.com/docview/447794301/abstract/4BD66C646ED14D6BPQ/1?parentSessionId=fFncVPaFGfc7KFqMfOImzpcXRf1o5q7qrDjaFbQv9oI%3D&#

McCutcheon, G., Farnham, J., & Cantin, L. (2005). Emergency contraception. *Canadian Medical Association. Journal: CMAJ,* 173(6), 575.

Murray, G., & Todkill, A. M. (2006). Privacy issues and Plan B: The Canadian Pharmacists Association responds. *Canadian Medical Association. Journal: CMAJ,* 174(1), 64–66.

NAPRA (2017) *National Drug Scheduling Factors Schedule I - NAPRA*, *National Drug Scheduling Factors Schedule I*. Available at: https://www.napra.ca/wp-content/uploads/2022/08/NAPRA-NDSAC-Scheduling-Factors-September-2017.pdf

Nguyen, T. (2005). Plan B - like it or not. *Canadian Pharmaceutical Journal*, 138(4), 12.

Osmond, B. (2000). Access to the morning-after pill in BC. *Canadian Medical Association. Journal: CMAJ*, 162(11), 1554–1554.

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., & Brennan, S. E. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *International Journal of Surgery*, 88, 105906.

Pancham, A., & Dunn, S. (2007). Emergency contraception in Canada: An overview and recent developments. *Canadian Journal of Human Sexuality*, 16(3/4), 129.

Rhyno, C. (2001a). Emergency contraception: Supply in demand. *Canadian Pharmacists Journal*, 134(10), 15.

Rhyno, C. (2001b). Switching to Plan B: While the makers of Canada's first emergency contraception pill are abandoning the market because of slow sales, Saskatchewan is poised to become one of the first to approve another product, plan B, for sale from pharmacies without a doctor's prescription. *Canadian Pharmacists Journal*, 134(2), 19.

Schiappacasse, V., & Diaz, S. (2006). Access to emergency contraception. *International Journal of Gynecology and Obstetrics*, 94(3), 301–309. https://doi.org/10.1016/j.ijgo.2006.04.017

Sibbald, B. (1999). With teen pregnancies skyrocketing, ob/gyns seek support for nonprescription "morning-after pill". *Canadian Medical Association. Journal: CMAJ*, 161(7), 855.

Sibbald, B. (2000). Despite some opposition, BC pharmacists to dispense morning-after pill without prescription. *Canadian Medical Association. Journal: CMAJ*

Sibbald, B. (2001). Over-the-counter emergency contraception available soon across country? *Canadian Medical Association. Journal: CMAJ*.

Sibbald, B. (2005). Nonprescription status for emergency contraception. *Canadian Medical Association. Journal: CMAJ*, 172(7), 861–862.

Shoveller, J., Chabot, C., Soon, J. A., & Levine, M. (2007). Identifying barriers to emergency contraception use among young women from various sociocultural groups in British Columbia, Canada. *Perspectives on Sexual and Reproductive Health*, 39(1), 13–20. https://doi.org/10.1363/3901307

Soon, J. A., Levine, M., Ensom, M. H., Gardner, J. S., Edmondson, H. M., & Fielding, D. W. (2002). The developing role of pharmacists in patient access to emergency contraception. *Disease Management & Health Outcomes*, 10, 601–611.

Soon, J. A., Levine, M., Osmond, B. L., Ensom, M. H., & Fielding, D. W. (2004). Provision of emergency contraceptives by pharmacists: British Columbia experience a template for other provinces. *Canadian Pharmacists Journal*, 137(6), 23–29.

Soon, J. A., Levine, M., Osmond, B. L., Ensom, M. H., & Fielding, D. W. (2005). Effects of making emergency contraception available without a physician's prescription: A population-based study. *Canadian Medical Association. Journal: CMAJ,* 172(7), 878–883.

Tricco, A. C., Lillie, E., Zarin, W., O'Brien, K. K., Colquhoun, H., Levac, D., Moher, D., Peters, M. D. J., Horsley, T., Weeks, L., Hempel, S., Akl, E. A., Chang, C., McGowan, J.,

Stewart, L., Hartling, L., Aldcroft, A., Wilson, M. G., Garritty, C., … Straus, S. E. (2018). PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Annals of Internal Medicine*, 169(7), 467–473. https://doi.org/10.7326/M18-0850

Trussell, J. (2012). Emergency contraception: Hopes and realities. In *Emergency contraception: The story of a global reproductive health technology*, Foster, A. M., & Wynn, L. L. (Eds.). Palgrave Macmillan: New York; pp 19-35. https://doi.org/10.1057/9781137016485

WHO. (2021). *Emergency contraception*. https://www.who.int/news-room/fact-sheets/detail/emergency-contraception

Wynn, L. L., Erdman, J. N., Foster, A. M., & Trussell, J. (2007). Harm reduction or women's rights? Debating access to emergency contraceptive pills in Canada and the United States. *Studies in Family Planning*, 38(4), 253–267.

Yuksel, N., Schindel, T., Siyam, T., & Hocevar, S. (2011). Pharmacists' beliefs about Plan B as an over-the-counter product. *Canadian Pharmacists Journal*, 144(5), E40.

Table 1. Inclusion criteria for published source material in this scoping review on the regulatory journey of progestin-only emergency contraceptive pills in Canada

Characteristic	Inclusion criteria	Exclusion criteria
Country	Canada or includes Canada	Country other than Canada
Concept	Regulatory history of progestin-only emergency contraceptive pills	Topic other than regulatory history of progestin-only emergency contraceptive pills
Date	1995-2020 (inclusive)	Published before 1995 or after 2020
Language	French or English	Language other than French and English

Table 2: Example of search strategy for databases included in this scoping review on the regulatory journey of progestin-only emergency contraceptive pills in Canada

Step	Terms used in Ovid (Medline)
1	Levonorgestrel/
2	((emergency or postcoital) adj3 contracept*).ti,ab.
3	Government Regulation/
4	exp Canada/
5	exp Contraceptives, Postcoital/
6	regulat*.ti,ab.
7	contraceptive, oral/ or exp contraceptives, postcoital/
8	legislat*.ti,ab.
9	(Nonprescription adj3 Drug).ab,ti.
10	health policy/
11	public policy/
12	deregulat*.ab,ti.
13	access*.ab,ti.
14	health service.ti,ab.
15	1 or 2 or 5 or 7
16	3 or 6 or 8 or 9 or 10 or 11 or 12 or 13 or 14
17	4 and 15 and 16
18	Remove duplicates from 17
19	limit 18 to yr="1995 to 2020"
Results	**94**

Table 3: Characteristics of the literature included in this scoping review on the regulatory journey of progestin-only emergency contraceptive pills in Canada

Characteristic	Frequency
Type of source material	
Article in peer-reviewed journal/scholarly source	16
News article	21
Other documents/websites	9
Geographic focus	
Canada (national)	28
Alberta	1
British Columbia	6
New Brunswick	1
Ontario	6
Other (Manitoba, Nova Scotia, Quebec Saskatchewan)	4
Stage of regulatory journey	
Initial approval	2
Prescription-only status	8
Behind-the-counter status	27
Over-the-counter status	7
More than one regulatory period	2

Table 4. Summary of scholarly articles, book chapters, and abstracts included in this scoping review on the regulatory journey of progestin-only emergency contraceptive pills in Canada (N=16)

	Author and year	Aim/objective	Study design	Regulatory status	Geographic area	Key findings
1	Borsella & Foster, 2020	To obtain information about the availability and cost of progestin-only emergency contraception (EC) in pharmacies of New Brunswick	Mystery client study	Schedule III	New Brunswick	Progestin-only EC was easily accessible in New Brunswick pharmacies, with representatives providing accurate information to an adolescent mystery client over the phone.
2	Chaumont & Foster, 2017	To assess the knowledge, attitudes, and practice patterns of community pharmacists in Ontario with respect to all modalities of EC.	Survey of pharmacies	Schedule III	Ontario	Surveyed pharmacies in Ontario had progestin-only EC in stock; some required those seeking EC to consult with a pharmacy representative, effectively making the drug available behind the counter.
3	Cohen et al., 2004	To evaluate whether participating pharmacists were following project protocol regarding EC information and dispensing.	Mystery client study	Schedule I	National	Immediate access to EC is critically important but there were delays in availability and limited pharmacist guidance on usage and efficacy.
4	Cook et al., 2006	To provide an overview of emergency contraception, abortion, and evidence-based law	Legal review	Schedule II	International	Health ministries play a critical role in providing evidence-based guidance to ensure proper and accessible care for preventing unintended pregnancies.
5	Dunn et al., 2008	To evaluate the availability of Plan B® in Ontario pharmacies and pharmacy compliance with Schedule II regulatory status	Survey of pharmacies	Schedule III	Ontario	The regulatory change for Plan B® did not significantly affect pharmacy provision. Availability increased, but barriers to access remained.
6	Dunn et al., 2003b	To develop and evaluate a program to provide EC directly in pharmacies	Project evaluation	Schedule I	Ontario	More than half of the women were able to access EC within 24 hours after intercourse, including evenings and weekends.
7	Ederman, 2012	Explore the complex and contentious political dynamics surrounding the regulatory status of EC in Canada	Policy and document review	Schedule I,II,III	Federal	The deregulation process involved discussions between Health Canada and professional associations and advocacy organizations. Tensions arose between professional groups and debates centered on the need for counseling and scope of practice.
8	Hukku et al., 2018	To explore the knowledge and experiences of young adults with EC in Ontario	Survey of young adults and follow-up interviews	Schedule III	Ontario	Lack of knowledge, negative health encounters, and stigma shaped women’s perspectives on the availability and accessibility of emergency contraception in Ontario.
9	Langille et al., 2012	To explore family physicians’ knowledge of and attitudes toward EC in Nova Scotia	Survey of family physicians	Schedule III	Nova Scotia	Few physicians prescribed EC in advance. Younger and woman physicians were more proactive with EC provision and had better knowledge of Plan B ®.
10	Pancham & Dunn, 2007	To give an overview of recent changes and developments of EC in Canada	Policy review	Schedule II	National	The new regulatory status of EC in pharmacies eliminated the need for a prescription and enhanced accessibility and convenience, despite existing barriers such as misconceptions, limited access in rural areas, and consultation fees.
11	Shoveller & al., 2007	To assess women’s perceptions of barriers to EC access	In-depth interviews	Schedule II	British Columbia	Ethnically diverse women’s awareness of EC influenced by knowledge and conservative cultural or social beliefs.
12	Soon et al., 2002	To provide an update on the status of progestin-only EC	Review	Schedule II	National	Increased EC availability in British Columbia aimed to reduce unintended pregnancies, improve awareness, and provide accessible, safe options through community pharmacies.
13	Soon et al., 2004	To provide an update on EC distribution in British Columbia	Review	Schedule II	British Columbia	Consensus favors non-prescription EC in pharmacies for preventing unwanted pregnancies, influenced by British Columbia's successful deregulation.

14	Soon et al., 2005	To identify changes in EC use after the switch to Schedule II status	Population-based cohort study	Schedule II	British Columbia	British Columbia granted pharmacists prescriptive authority for EC in 2000, doubling usage in the second year of availability, despite barriers of counseling and service fees.
15	Wynn et al., 2007	To compare the ethical pivot points in debates over nonprescription access to EC in Canada and the United States.	Policy review	Schedule II	National	The move to behind-the-counter access for EC sparked debates on drug scheduling, mechanism of action, barriers to access, privacy concerns, and promotion of harm reduction, women's rights, and reproductive choice.
16	Yuksel et al., 2011	To explore pharmacists' beliefs about Plan B® as a Schedule III drug	Survey of community pharmacists	Schedule III	Alberta	Although pharmacists supported over-the-counter status, most stored EC behind the counter in Alberta.

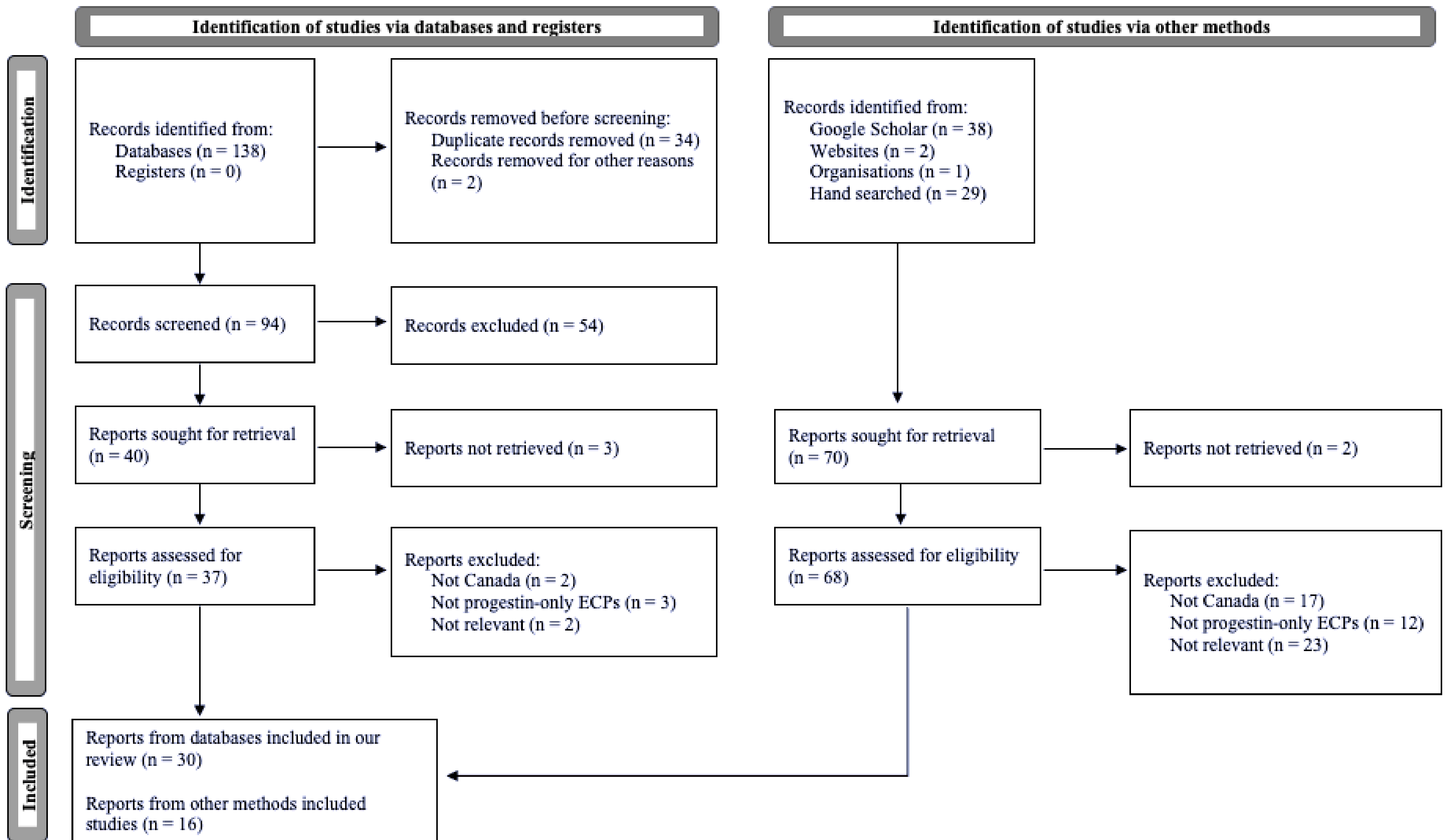

Figure 1: PRISMA-ScR flow diagram of source material selection for this scoping review of the regulatory journey of progestin-only emergency contraceptive pills (ECPs) in Canada

Chapter 4: Article #2

We prepared this report for submission to the American Society of Emergency Contraception. The report conforms to the structural and formatting requirements of this organization.

The availability of emergency contraception pills after the over-the-counter status in Ottawa, Canada

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Executive summary

This report investigates the accessibility of progestin-only emergency contraceptive pills (ECPs) in the Greater Ottawa region, covering both Ontario and Quebec. Despite being available for two decades, challenges persist, with many pharmacies, including the majority in Ontario, keeping progestin-only ECPs behind-the-counter. Ulipristal acetate (UPA) is regulated as a prescription drug across Canada.

The study's objective was to assess the availability and accessibility of ECPs in the region. Using a mystery client approach, volunteers collected data on on-shelf availability, product details, and pricing, interacting with pharmacy representatives to gather information on restrictions and UPA availability. The analysis of 124 visits to 99 pharmacies revealed a prevalent practice of keeping progestin-only ECPs behind-the-counter, even in provinces with different regulatory statuses. Men faced restrictions in purchasing progestin-only ECPs and UPA availability was limited.

The discussion highlights the potential delays and barriers to care resulting from keeping progestin-only ECPs behind-the-counter. Urgent measures are recommended, including engaging health professionals, encouraging clinician prescriptions for UPA, and informing potential seekers about available options. These strategies aim to improve overall accessibility to both progestin-only ECPs and UPA in the Greater Ottawa region.

Introduction

Emergency contraceptives include a diverse array of methods used after sexual intercourse to prevent pregnancy. In Canada, the available modalities of emergency contraception (EC) are combined hormonal pills (the Yuzpe method), progestin-only emergency contraceptive pills (ECPs), ulipristal acetate (UPA), and the copper-T intrauterine device (IUD) (Trussell, 2012). Progestin-only ECPs are the most widely used type of EC and have been available in Canada for more than two decades (Soon et al., 2005). In 2008, Health Canada, the federal agency charged with determining the regulatory status of drugs, approved these pills as a Schedule III drug (Sibbald, 2001; World Health Organization, 2021). Thus, at the federal level, progestin-only ECPs are permitted for sale over-the-counter (OTC) without the need for a prescription or a consultation with a pharmacist (Eggertson, 2008). However, because health care policy is implemented at the provincial level some provinces continue to regulate progestin-only ECPs as a Schedule II drug. Indeed, in both Saskatchewan and Quebec procuring progestin-only ECPs requires a consultation with a pharmacist who can then prescribe the medication. As a result, progestin-only ECPs are carried behind-the-counter (BTC) as a matter of course in some geographic areas of the country (Ederman, 2012).

Multiple brands of progestin-only ECPs are available in Canada, but Plan B® is the most widely known and the phrase has become synonymous with EC. In March 2014, Health Canada issued a statement indicating that progestin-only ECPs were less effective if taken by women weighing more than 165 pounds and ineffective if taken by women weighing more than 175 pounds (Vogel, 2015).

In 2015, UPA, a second-generation dedicated ECP, became available in Canada for post-coital use as a Schedule I drug, meaning that it requires a prescription for use (Praditpan et al., 2017). Before this change in the product monograph, UPA had only been available in low doses for the

treatment of uterine fibroids. UPA is more effective than progestin-only ECPs when used 73-120 hours after sexual intercourse and when used by women weighing more than 165 pounds (Praditpan et al., 2017; Smith et al., 2017; Shen et al., 2019). Because UPA had originally been approved for a different indication, there was little attention paid to its approval for post-coital use and traditional “detailing” did not occur. Consequently, there is little documented use of UPA in Canada.

Canada has universal health insurance coverage through the Canada Health Act. However, Canada does not have a universal drug benefit plan. Further, provincial management of health care means that there are a range of policies that govern the availability of services and the cost of drugs. In most parts of the country, OTC drugs, such as progestin-only ECPs, must be paid for out-of-pocket at the point of sale. Schedule I drugs, such as UPA, may or may not be covered through public or private drug benefit programs. As a result, the cost of EC to potential users can vary significantly by both province and modality.

However, studies conducted over the last decade in Canada have revealed several barriers to accessible EC. In provinces such as Ontario and New Brunswick, where progestin-only ECPs are supposed to be available OTC, studies indicate that obtaining these drugs often requires an in-person interaction with a pharmacy representative (Borsella & Foster; Chaumont & Foster,2017). Studies in multiple provinces have shown that misinformation about the regulatory and medical status of ECPs is high among pharmacists (Borsella & Foster,2020; Wong et al., 2017). The price associated with obtaining progestin-only ECPs can also pose a barrier, especially among adolescents (Brogan, 2019).

In the summer of 2022, a team at the University of Ottawa (Ontario, Canada) partnered with the American Society of Emergency Contraception (ASEC) to conduct a study on the availability

and accessibility of ECPs in Canada. In this report, we share the findings from the Greater Ottawa area.

Methods

In 2016, ASEC published a study on the availability and accessibility of progestin-only ECPs (Cleland et al., 2016). This study employed a mystery client study design to crowd-source information about the on-shelf availability of progestin-only ECPs and detailed information about brands, prices, and locations. In 2022, ASEC decided to replicate this study and add a Canadian component.

Study location

The Greater Ottawa region stands out for its vibrant cultural heritage and historical landmarks. Nestled in the eastern part of Ontario, it encompasses the national capital of Canada and extends across the Ottawa River into Gatineau, Quebec (see Fig. 1). Notably, Ottawa serves as the seat of the Canadian government, situated on the unceded and unsurrendered territory of the Anishinaabe Algonquin People.

Despite their proximity, the regulatory landscape for progestin-only emergency contraceptive pills differs significantly in this region. In Ontario, these pills have been available over-the-counter without prescription or consultation since 2008 (Chaumont & Foster, 2017; Eggertson, 2008). In contrast, in the province of Quebec, access to emergency contraception involves obtaining the medication through a pharmacist-prescribed encounter (Soper & Di Meglio, 2020; LQ 2011, c 37; Éditeur officiel du Québec, 2011).

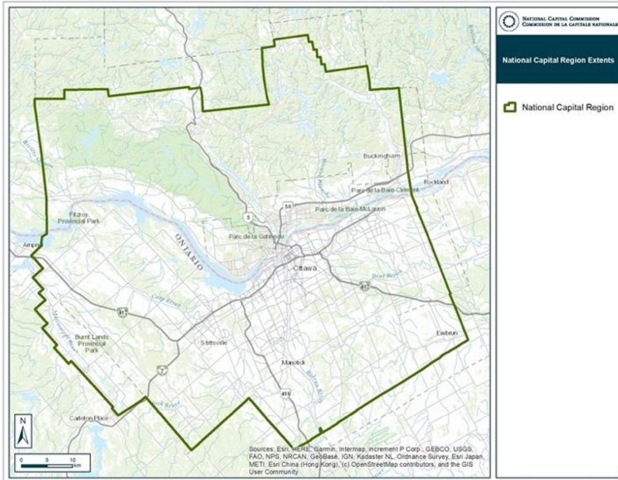

Figure 1: Map of the greater Ottawa Region (Harris, 2019)

Data collection

A team of 15 student-volunteers from the University of Ottawa visited local pharmacies in the Greater Ottawa area in the summer and fall of 2022. We provided volunteers with a modified version of the questionnaire developed by ASEC in both English and French (see Annex A for the English version). After documenting the name, location, and type of pharmacy, we asked our student-volunteers to document the on-shelf availability, brands, price, and location of progestin-only ECPs. We then asked the mystery clients to approach a pharmacy representative and obtain more information about identification, age, and gender requirements for purchasing progestin-only ECPs and any rationale for why the product was not available OTC, if applicable. We also asked mystery clients to ask about the availability and process of obtaining UPA. Student-volunteers then recorded their observations, experiences, impressions, and reactions on Google Forms.

Data analysis

We used the pharmacy as the unit of analysis; when more than one volunteer visited the same individual pharmacy we aggregated the results and reported on the "most accessible"

encounter. We exported information from Google Forms to Microsoft Excel® for analysis. We analyzed the quantitative results using descriptive statistics, focusing on frequencies and cross-tabulations. We analyzed the written and open-ended portions of the questionnaire for content and themes using both inductive and deductive techniques.

Ethical considerations

Based on Article 2.1 of the Tri-Council Policy Statement (Government of Canada, 2022) the Office of Research Ethics and Integrity at the University of Ottawa has determined that this type of study does not need a Research Ethics Board review, as it constitutes an evaluation of professional services and does not involve human subjects. However, we have masked or redacted all identifying information about individual pharmacies and their employees.

Results

Pharmacy characteristics

Our team conducted 124 visits to 99 unique pharmacies in the Greater Ottawa region. We provide basic information about these pharmacies on Table 1. We visited 88 pharmacies (89%) in Ontario and 11 pharmacies (11%) in Quebec. The majority of the pharmacies that we visited were chain pharmacies (n=72, 73%) and in urban or suburban areas (n=92, 93%).

Table 1: Characteristics of retail pharmacies visited in the Greater Ottawa region (N=99)

Characteristic	Number (%)
Province	
Ontario	88 (89%)
Quebec	11 (11%)
Type of pharmacy	
Chain	72 (73%)
Independent	27 (27%)
Region	
Urban	30 (30%)
Suburban	62 (33%)
Rural	7 (7%)

Area/Neighborhood	
Nepean	17 (17%)
Orleans	15 (15%)
Downtown	14 (14%)
Gatineau (Quebec)	11 (11%)
Centretown/Glebe	7 (7%)
Kanata	7 (7%)
Kemptville	7 (7%)
Manotick	7 (7%)
Gloucester	5 (5%)
Other	9 (9%)

Availability of progestin-only ECPs

Of the 99 pharmacies included in the study, 19 pharmacies (19%) had progestin-only ECPs available on the shelf at the time of our visit. Given that in Quebec procuring progestin-only ECPs requires a consultation with a pharmacist, it is not surprising that none of the 11 pharmacies we visited had on-shelf availability. However, in Ontario only one in five pharmacies had progestin-only ECPs available on the shelf and in one case the product was available but behind a security device that required engagement with a pharmacy representative to unlock. In three other Ontario pharmacies (3% of those in Ontario) there was a place on the shelf but it was empty. In all of the other Ontario pharmacies (n=66, 75%) there were no indications that progestin-only ECPs were ever available OTC. Notably, only three independent pharmacies in Ontario (3%) carried progestin-only ECPs on the shelf, compared to 15 (17%) of chain pharmacies. One pharmacy uniquely stored the medication both on the shelf and behind the counter. Progestin-only ECPs that were on the shelf were primarily located in the family planning or the family planning/feminine products and care aisle of the pharmacy. Reasons provided by pharmacy staff for not storing progestin-only ECPs on the shelf included concerns about theft and cost and one chain pharmacy representative mentioned that their system, Pharmacare, mandates placing progestin-only ECPs BTC.

Multiple brands of progestin-only emergency contraceptive pills (ECPs) were accessible in Ontario, including Plan B® (1.5mg), Contingency One®, and Back Up Plan One Step®. Plan B® was stocked in 71 (87%) Ontario pharmacies, with prices ranging from CAD $21.45 to CAD $60.00 (average CAD $32.78). Contingency One® was available in 22 (27%) Ontario pharmacies, priced between CAD $15.00 and CAD $36.15 (average CAD $25.62). Back-Up One Step® could be found in 7 (9%) Ontario pharmacies, with prices ranging from CAD $14.68 to CAD $29.99 (average CAD $20.72). While volunteers reported the availability of several other medications, prices were not recorded. In the Gatineau area, available emergency contraception brands include Backup Plan® and Plan B®, with prices ranging from CAD $19.00 to CAD $35.00 (average CAD $25.39).

Identification, age, and gender requirements for obtaining progestin-only ECPs

In 93% (n= 82) of pharmacies in Ontario, our mystery client interacted with a pharmacy representative to collect additional information about requirements for obtaining progestin-only ECPs. In almost all cases, the mystery client interacted with a pharmacist (n=51, 82%) or a pharmacy technician/assistant (n=19, 23%). In only one instance did a pharmacy representative decline to answer questions. Because of the pharmacy consultation requirement in Quebec, we interacted with a pharmacy representative in all 11 encounters.

In Ontario, 9% (7 of 74 encounters) reported that an EC seeker needed to present identification to obtain progestin-only ECPs. Further, 15% (11 of 74 encounters) of pharmacy representatives reported that EC seekers needed to be at least 14 to 20 years of age to obtain progestin-only ECPs and 6% (4 encounters) of pharmacy representatives reported that men/boys could not purchase progestin-only ECPs.

Concerning progestin-only ECPs in Quebec pharmacies, all 11 (100%) indicated that they do not permit men to purchase emergency contraceptive pills from pharmacies. Furthermore, among 3 (27%) pharmacies imposed an age limit of 14, with one pharmacy noting that parental consent is required if the patient is 13 or younger.

Availability of UPA

We obtained information about the availability of UPA from 77 pharmacies; 66 in Ontario and 11 in Quebec. In Ontario, only 7 pharmacies (11% of those consulted) had UPA in stock at the time of the visit. A handful of other pharmacy representatives reported that they could order UPA if presented with a prescription. In Quebec, each pharmacy we visited stocked ELLA®, and the prices of UPA ranged from CAD $30.00 to CAD $50.00.

Quality of the experience of seeking emergency contraception

Our student-volunteers reported a range of emotions while seeking progestin-only ECPs or information about EC. We report on how they characterized these visits on Table 2. Our mystery clients characterized obtaining progestin-only ECPs as being very difficult (n=26, 21%) or somewhat difficult (n=47, 38%) in the majority of visits (59% overall). In contrast, mystery clients report that obtaining progestin-only ECPs was very easy in 10% (n=12) of all visits.

Table 2: Characterization of the visit to the pharmacy to obtain progestin-only ECPs (N=124)

Characterization	Number (%)
Very difficult	26 (21%)
Somewhat difficult	47 (38%)
Somewhat easy	37 (30%)
Very easy	12 (10%)
No answer given	2 (2%)

Many of our student volunteers expanded on the reasons that they characterized their visit in the way that they did. Some (n=22, 18% of all visits) reported that they felt discouraged or

confused when trying to obtain information about EC or felt uncomfortable and/or nervous. As on mystery client reported:

> I would definitely feel uncomfortable buying EC at this store. There's no OTC EC in the store and no signage in the aisles to indicate where EC would be, so you're forced to go to the counter and ask. It was super busy even on a Tuesday at 8 pm when my town is usually not busy. Other people asked to go in front of me because I had several questions to ask. The pharmacist had a lot of trouble finding out the price of Ella without insurance. The process took several minutes and he mentioned that the computer system glitched a couple times. I would also be uncomfortable since only a male pharmacist was on duty" (Chain pharmacy, Kemptville, ON).

Another mystery client reported:

> Very uncomfortable. I saw none on the shelves. It was very busy, and all pharmacy clerks and pharmacists were male and were not interested in talking. I asked one clerk, and he told me to go to consultation and the pharmacist would answer me. I waited awkwardly as each one looked at me but did not want to address me while other customers waited and stared at me. The pharmacist insisted it was on the shelf but found none then proceeded to tell me it was out of stock. When asked about brands he said he knows they carry two, Plan B and he is not sure of the other name. I felt rushed as it was busy so I asked as much as I could remember and left. (Chain pharmacy, Nepean Ottawa, ON).

A smaller subset of mystery clients (n=4, 3%) specifically mentioned having privacy concerns about the interaction. For example, in describing a visit to an independent pharmacy in Manotick, one student-volunteer reported "[I was] required to ask questions in a crowded environment. [I] repeatedly had to ask to talk about EC. When asking for the brand name of the product, the pharmacist repeatedly said they only sold Plan B, despite the generic brand being the only one offered."

Our student volunteers also detailed a number of examples of misinformation expressed by pharmacy representatives. For example, when visiting an independent pharmacy in Gloucester, Ottawa one volunteer reported, "The pharmacy technician was certain that ID was required and that you must be 18+ to buy it, making it difficult to access". Another explained that after visiting a chain pharmacy in Nepean, "I was shocked the pharmacist did not have any generic pills and

only had the brand Plan B. I felt a little uncomfortable having to explain that [progestin-only ECPs] are available as OTC and having to explain the current regulatory status with no proper explanation of why EC is not available on the shelf."

In contrast, a small number (n=9, 7%) reported having a positive experience. As one student-volunteer explained:

> I spoke with a pharmacy technician at this store; I felt very comfortable speaking with her, and all my questions were answered. Although the EC was located behind the pharmacy counter and not on the shelves, I was quickly guided to where they had EC after asking a worker. I do not think someone buying EC at this store would face any obstacles/feel uncomfortable due to the friendliness and professionalism of the workers" (Chain pharmacy, Sandy Hill, Ottawa).

Discussion

Over two decades after Health Canada granted OTC status to progestin-only ECPs our study reveals critical shortcomings in EC service delivery by pharmacists in Ontario. Despite the Schedule III status, the availability of progestin-only ECPs in Ontario is only marginally better than in Quebec, showcasing that deregulation alone is insufficient to ensure greater access. This situation aligns with similar findings in prior Canadian studies (Borsella & Foster, 2020; Chaumont et al., 2017; Cohen et al., 2004; Dunn et al., 2008; Wong et al., 2017) emphasizing the need for continued engagement with pharmacists, particularly those affiliated with chain pharmacies.

A prevalent issue highlighted in our study is the persistent misinformation circulating among pharmacy personnel regarding progestin-only ECPs. This includes misinformation about ID, age, and gender requirements for purchase. Our mystery clients reported discomfort during these interactions which suggests that actual progestin-only ECP seekers would likely encounter similar challenges. To address this, undertaking strategies to disseminate accurate

information to potential EC users in Greater Ottawa and identifying ways to direct them to more accessible venues is warranted. Developing an "EC pharmacy report card" for the region could guide individual pharmacies with more consistent availability and better accessibility.

Additionally, our research shows that seven years post-approval of UPA for post-coital use in Canada there is a notable lack of awareness and availability. Our findings align with other studies that indicate a low prescription rate for UPA in both Canada (Chan et al., 2020) and the US (Cleland et al., 2016). Efforts to increase awareness about UPA among potential users, engage with prescribers about the relative benefits of UPA for particular groups of patients, and work with pharmacies to ensure the product is stocked are needed. Collaborating with community organizations on a multi-faceted strategy, with special attention to the unique situation in Quebec, could be successful.

Limitations

Several limitations exist in this study. Although we purposively selected pharmacies in different regions and neighbourhoods of Greater Ottawa, we did not visit pharmacies in all areas. Thus, although we visited a large number of pharmacies we caution against generalizing the results. Further, not all student-volunteers approached pharmacists for additional information, making the data on identification requirements, age restrictions, and gender requirements less robust. These interactions might also have yielded different results had the student-volunteer encountered a different individual. However, despite these limitations, this study represents the first of its kind in the Greater Ottawa region and sheds light on the availability and accessibility of EC in Canada’s capital.

Conclusion

In conclusion, this study underscores the persistent challenges surrounding access to progestin-only ECPs in Canadian pharmacies. The findings showcase the gap between regulatory status and real-world availability in progestin-only ECPs and the lack of availability of UPA in Ontario. Developing resources to help EC seekers identify venues with on-shelf progestin-only ECP products could help ensure timely access. Our results also shed light on the need for increased awareness about UPA, emphasizing the importance of education among both the public and healthcare professionals.

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Conflict of Interest

The authors declare no conflict of interest.

Abbreviations

ASEC	American Society of Emergency Contraception
BTC	Behind the counter
EC	Emergency contraception
ECP	Emergency contraceptive pill
IUD	Intrauterine device
OTC	Over the counter
UPA	Ulipristal acetate

References

Borsella, M., & Foster, A. M. (2020). Exploring the Availability of Emergency Contraception in New Brunswick Pharmacies: A Mystery-Client Telephone Study. Pharmacy, 8(2), Article 2. https://doi.org/10.3390/pharmacy8020076

Brogan, N. R. (2019). Exploring the Contraceptive Experiences of Adolescents Living in Rural Ontario [Thesis, Université d'Ottawa / University of Ottawa]. https://doi.org/10.20381/ruor-24098

Cleland, K., Bass, J., Doci, F., & Foster, A. M. (2016). Access to Emergency Contraception in the Over-the-Counter Era. *Women's Health Issues*, *26*(6), 622–627. https://doi.org/10.1016/j.whi.2016.08.003

Chaumont, A., & Foster, A. M. (2017). The not so over-the-counter status of emergency contraception in Ontario: A mixed methods study with pharmacists. FACETS, 2, 429–439. https://doi.org/10.1139/facets-2017-0024

Ederman, J. N. (2012). *Canada: Competing Frames of Access and Authority*. Palgrave Macmillan. http://ebookcentral.proquest.com/lib/ottawa/detail.action?docID=912248

Éditeur officiel du Québec. (2011). *LQ 2011, c 37 | Loi modifiant la Loi sur la pharmacie*. CanLII. https://www.canlii.org/fr/qc/legis/loisa/lq-2011-c-37/121743/lq-2011-c-37.html

Eggertson, L. (2008). Plan B comes out from behind the counter. *CMAJ: Canadian Medical Association Journal = Journal de l'Association Medicale Canadienne*, *178*(13), 1645–1646. https://doi.org/10.1503/cmaj.080809

Government of Canada, I. A. P. on R. E. (2022). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)*. https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

Harris, J. (2019). *National Capital Region | The Canadian Encyclopedia*. https://www.thecanadianencyclopedia.ca/en/article/national-capital-region

Praditpan, P., Hamouie, A., Basaraba, C. N., Nandakumar, R., Cremers, S., Davis, A. R., & Westhoff, C. L. (2017). Pharmacokinetics of levonorgestrel and ulipristal acetate emergency contraception in women with normal and obese body mass index. *Contraception*, *95*(5), 464–469. https://doi.org/10.1016/j.contraception.2017.01.004

Sibbald, B. (2001). Over-the-counter emergency contraception available soon across country? *CMAJ: Canadian Medical Association Journal*, *164*(6), 849.

Soon, J. A., Levine, M., Osmond, B. L., Ensom, M. H. H., & Fielding, D. W. (2005). Effects of making emergency contraception available without a physician's prescription: A population-based study. *CMAJ*, *172*(7), 878–883. https://doi.org/10.1503/cmaj.045019

Soper, K., & Di Meglio, G. (2020). Accessibility of emergency contraception for adolescents in Quebec community pharmacies. *Paediatrics & Child Health*, *25*(6), 385–388. https://doi.org/10.1093/pch/pxz109

Trussell, J. (2012). Emergency Contraception: Hopes and Realities. In *Emergency Contraception* (pp. 19–35). Palgrave Macmillan US. https://doi.org/10.1057/9781137016485_2

Vogel, L. (2015). Rethink weight limits on morning-after pill. *CMAJ: Canadian Medical Association Journal*, *187*(10), 719–721. https://doi.org/10.1503/cmaj.109-5098

World Health Organization. (2021). *Emergency contraception*. https://www.who.int/news-room/fact-sheets/detail/emergency-contraception

Annex A: Mystery client questionnaire (English version)

ASEC EC Access & Price Survey, 2022

ASEC and a research team at the University of Ottawa are collecting data on the pricing and display of emergency contraception (EC) across Canada. Although Health Canada allows levonorgestrel EC (like Plan B, etc.) to be sold directly on the shelf to anyone of any age with no restrictions, reports from around the country indicate that in many places, it's not that simple. We are asking you to take a trip to your local pharmacy or store and let us know how levonorgestrel EC is being sold and how much it costs. We would also like to gather information on the accessibility and associated cost of ulipristal acetate EC (ella®).

If you are reporting data for more than one store, please fill out a survey for each store. If possible, please bring your phone or tablet with you and fill out the survey while in the store. You may also print a copy of the questions for collecting data to fill out the survey later at this link:
https://drive.google.com/file/d/1K1W9OkGEg0TTQd6ucY9Jx4KLDc7xbixm/view?usp=sharing

Don't forget to fill out the final question to be included in a raffle for a CAD $50.00 gift card to www.amazon.ca! 4 prizes will be awarded to those who provide complete responses to the survey.

Thank you very much for your participation! If you have any questions, please contact Kelly Cleland or Nicola Brogan at . You can also contact Émilie Friesen or Dr. Angel M. Foster ( ) with any questions!

About you
Your name:
Age: *
Gender:*
Email address:*

Pharmacy details
6. Store name:*
7. Store address or street name:*
8. City in which the store is located:*
9. Province/territory in which the store is located:*
10. Mark only one oval.
- ❑ Urban
- ❑ Suburban
- ❑ Rural
- ❑ Reserve
- ❑ Other:

OTC Availability
Is levonorgestrel EC (Plan B, etc) on the shelf?
- o Yes, the box is directly on the shelf and not locked up in any way
- o Yes, in a plastic box that has to be carried to the counter and unlocked by an employee
- o Yes, in a locked display case in the aisle

- There is a space for EC, but it's currently empty
- No, and there's no space for it

If on the shelf, where is EC located within the store?

- In the family planning aisle (near condoms and pregnancy tests)
- In the feminine care aisle (near tampons and pads)
- In front of the pharmacy counter
- Other:

Do you see any signs about a limit on how many packs of EC you can purchase? Please describe or upload a photo in the next question.

Upload a photo of signage limiting purchases here.
If not on the shelf, where is EC available in the store?

- Behind the pharmacy counter
- Behind the front/cashier's counter
- EC is not available in this store at all
- Other:

If EC is not available in the store at all, please ask a staff member why and note their answer here:

Products & Prices
If EC is available in the store, please check the shelf and record the prices of each product. If EC is not on the shelf ask a store employee the following: "What brands does the store carry and how much does each brand cost?"

- Brand #1 (Specify)
  Price (leave blank if not available)
- Brand #2 (Specify)
  Price (leave blank if not available)
- Brand #3 (Specify)
  Price (leave blank if not available)
- Brand #4 (Specify)
  Price (leave blank if not available)

Please feel free to upload photos of how EC is displayed

Purchase experience
In your experience, how easy or difficult was it to locate EC at this store?

- Very easy
- Somewhat easy
- Somewhat difficult
- Very difficult

Do you have any comments about your experience of finding EC in the store? Do you think someone buying EC at this store would face obstacles or feel uncomfortable?

If you're comfortable doing so, please go to the pharmacy counter and ask the following questions: "Do you have to be a certain age to buy EC/the morning-after pill?" If yes, what age and do you have to show ID?

Please ask: "Can men buy this?"

Please ask: "Do you carry or ella (the prescription kind of EC)?

- If it's not in stock right now, can you order it? How long does that take?"
- If they carry ella, please ask: "How much does ella cost without insurance?"

Who answered your questions?

- Pharmacist
- Pharmacy technician
- Manager
- Cashier
- Don't know
- Other:

Do you have any additional comments about your experience looking for EC?

Would you like to be included in a raffle for a $50 gift card? 4 gift cards will be sent to randomly selected volunteers who complete at least one survey. If yes, please add your email address below.

Chapter 5: Discussion

Integration of results

Through this project, our primary goal was to provide a comprehensive review of the deregulation of progestin-only emergency contraception and assess the real-world availability of this Schedule III drug in the Greater Ottawa region. The results obtained from both components of this study highlight the complex nature of the availability and accessibility of progestin-only ECPs within the Canadian Health System.

Our project consolidates existing literature, examines the changes in the deregulation of progestin-only ECPs within the Canadian health system, and explores current stocking and service delivery practices in the capital city. Additionally, we delve into the ease of accessing both progestin-only ECPs and UPA. The findings from the two components of this project reveal significant gaps in the implementation of regulatory policy. In the Greater Ottawa area, both in Quebec and Ontario, many pharmacies continue to effectively require that EC seekers consult with a pharmacy representative and very few pharmacy representatives can provide information about or timely access to UPA. Our findings align with other studies in Ontario (Yuksel et al., 2011; Chaumont & Foster, 2017).

Progestin-only emergency contraceptive pills have long been acknowledged to be safe, effective, and essential for women or other individuals capable of pregnancy (Trussell et al., 2012; Ederman, 2012). Our findings from the scoping review highlight that prior to regulatory reform unnecessary barriers to access were imposed by restrictions on service delivery, leading to delays in use. These barriers included compromised privacy, increased costs, and potential conflicts with pharmacists exercising their right to conscientious objection (Flood et al., 2006).

Barriers to care

When Health Canada designated progestin-only ECPs as a Schedule III drug, the expectation was that this would facilitate prompt access to emergency contraception for anyone

seeking it. However, research indicates that despite the deregulation of EC, barriers to access persisted (CWHN, 2005; Eggertson, 2006b; Murray & Todkill, 2006). Our mystery client study in Greater Ottawa confirms the findings from these previous studies and indicates that in many pharmacies in both Ontario and Quebec, progestin-only EC is not available on the shelf. Volunteers posing as EC seekers reporting various degrees of difficulty obtaining progestin-only ECPs and information about UPA. This need for EC seekers to consult with a pharmacy representative to obtain progestin-only ECPs occurred in both independently owned and chain pharmacies. That pharmacy policies deviate from federal government recommendations and regulations raises concerns about the decision-making process among drugstore policymakers (Borsella & Foster, 2020). Our findings highlight the gap between policy enactment and policy implementation, even for a policy change that occurred more than a decade ago.

Progestin-only ECPs in pharmacies

The deregulation of progestin-only ECPs was anticipated to result in widespread access and enable individuals to easily purchase the drug from the shelf, seek guidance, and receive additional assistance from pharmacists as needed. Contrary to these expectations, we identified a number of cases where the pharmacy representative lacked awareness of the actual regulatory status of progestin-only EC or provided incorrect information (Soon et al., 2002). Some respondents indicated that EC had to be stored behind the counter due to regulations, others wrongly asserted that men could not purchase this medication for someone else. Several of our volunteers because turned away by pharmacy representatives because of their age or were concerned that this would happen. These findings reflect persistent stigmatization of emergency contraception use, disparities in how other Schedule III drugs are offered, and ongoing barriers to access (Shoveller et al., 2007).

Availability and dispensing practices of ulipristal acetate

Various factors can influence the stocking and dispensing practices of pharmacies and a perceived lack of demand can create limited availability. That most Canadians are unfamiliar with UPA means that few EC seekers are requesting prescriptions from clinicians. That few clinicians know about the availability of UPA and the relative benefits compared to progestin-only ECPs means that few are prescribing. As a result, most pharmacy representatives knew little about UPA and many did not have the drug in stock at the time of the mystery client visit. Notably, pharmacy representatives in Gatineau, Quebec, where pharmacists continue to have prescribing authority over progestin-only ECPs, exhibited more consistent knowledge of and reported availability of UPA. Given the safety and efficacy of UPA, our findings suggest there is an unexplored opportunity to increase the visibility of this technology and raise awareness about the drug on the Ontario side of Greater Ottawa.

Significance

Barrier-free access to emergency contraception is crucial for women's reproductive health and rights and addressing ongoing service delivery challenges in North America is critical (Ederman, 2012). That UPA continues to require a prescription in Canada limits its availability and accessibility and does not reflect the safety profile and efficacy of the drug (Borsella & Foster, 2020). Indeed, even though UPA was approved for post-coital use by Health Canada in 2015, it remains underutilized due to a lack of awareness among both providers and potential users. The regulatory journey of progestin-only EC sheds light on what might facilitate the deregulation of UPA. Namely, documenting the need for greater and more timely access, particularly to those who would most benefit from UPA (such as those weighing more than 165 pounds), conducting and rigorously evaluating a demonstration project to showcase the feasibility of deregulation, and lifting the voices of EC seekers and users could be effective strategies to persuade regulators of the need for reform. Our mystery client study provides some initial evidence that UPA is not widely available.

Our findings also have implications for the regulation of medication abortion drugs. The safety and efficacy of medication abortion with mifepristone and misoprostol is well documented and makes the regimen an appropriate candidate for Schedule II status (Gatter et al., 2015). Specifically, evidence from around the world shows, and the World Health Organization's safe abortion guidelines state, that medication abortion pills can be provided by a range of health service professionals (Ganatra, 2015). In the Canadian context, allowing pharmacists to prescribe mifepristone and misoprostol could increase access to this time-sensitive intervention. Using the journey of progestin-only ECPs as a roadmap will allow researchers, professional societies, and reproductive health, rights, and justice advocates to develop strategies to make the case for deregulation. As the current barriers to abortion access have been well documented, an important next step will be to develop a pilot intervention to establish feasibility, safety, and acceptability. It will also continue to be important to document the lived experiences of abortion seekers who experience barriers to timely care.

Future directions

The goal is to address policy implications for enhancing accessibility to reproductive medication, particularly abortion medication, without compromising safety (Cano & Foster, 2016; Eggertson, 2001).

Building upon the insights gained from the regulatory journey of progestin-only ECPs, we recognize the potential for valuable lessons in supporting the deregulation of other safe and effective reproductive health drugs in Canada. Notably, Ulipristal acetate, a second-generation dedicated ECP, has demonstrated enhanced effectiveness compared to progestin-only ECPs, particularly between hours 73-120 and when administered to patients over 165 pounds (Trussell 2012; WHO 2021). Despite being available over-the-counter in numerous countries and deregulated by the European Medicines Agency, Ulipristal acetate still requires a prescription in Canada. Similarly, Mifepristone, a pivotal component of the gold standard medication abortion

regimen, remains a Schedule I drug in Canada, contrary to global evidence supporting its safe and effective use through various health service providers and delivery strategies (Gatter et al., 2015).

Following the presentation of these two studies, our subsequent actions will involve advocating for the integration of evidence on safety and efficacy as a foundational element for regulatory change. This entails collaborating with a diverse range of healthcare providers, promoting effective communication, and implementing innovative strategies, including the introduction of advanced prescribing directives and the empowerment of pharmacists (Soon et al., 2004). To bolster this initiative, we will prioritize the development of resources and training programs for pharmacists, aligning them with scoping review materials to further enhance their proficiency in delivering high-quality care (Nguyen, 2005).

Engaging with stakeholders, including influential entities like the Society of Obstetricians and Gynecologists of Canada (SOGC), National Drug Scheduling Advisory Committee (NDSAC), Royal College of Physicians and Surgeons of Canada (RCPS), and Federation of Medical Women of Canada (FMWC), is imperative. Ongoing dialogue with these stakeholders aims to understand diverse perspectives and contribute to the deregulation of medication (Ederman, 2012). Another avenue involves increasing public education and awareness about reproductive health medications, access, and care, with an emphasis on evaluating public awareness for improved overall experiences (Whelan et al., 2011). We aim to pave the way for improved accessibility to reproductive health drugs in Canada.

The lessons learned and recommendations presented provide a comprehensive framework for advancing reproductive medication access. By fostering collaboration, engaging with key stakeholders, and promoting evidence-based policymaking, we can collectively work towards a regulatory environment that ensures safe and effective reproductive health drugs are readily accessible to those in need.

Limitations

This project has several limitations. As reported in Chapter 3, our scoping review only focused on the regulatory journey of progestin-only ECPs. Expanding the scope of the regulatory review to include other reproductive health drugs could provide greater insight into levers of change. Future research that explores this broader context and history is warranted. Although Greater Ottawa is an important region for exploring EC availability because it straddles two provinces, the results may not be transferable to other areas of Canada. Our findings related to progestin-only ECPs are consistent with findings from studies conducted in other provinces, but there is very little literature that explores the availability and accessibility of UPA. Although there is no reason to believe that Greater Ottawa would be an outlier, it will be important for future researchers to explore the availability and accessibility of UPA in other parts of Ontario and other provinces.

Positionality and reflexivity

When engaging in qualitative research, acknowledging one's positionality and practicing reflexivity is crucial. Positionality encompasses one's identity and life experiences, which can significantly influence the researcher’s perspectives and interpretation of data. Reflexivity involves the researcher recognizing their influences, experiences, and identities during the design, implementation, and analysis phases of the project and critically exploring how these dynamics might influence interpretations, recommendations, and conclusions.

Reflecting on my personal experiences, I recognize that I am a white, cisgender woman of reproductive age, fully bilingual, who grew up in a small town on the border of Quebec and Ontario. Transitioning to Ottawa, I became a registered nurse and worked in a tertiary trauma center for several years. This experience of caring for individuals in critical care settings fueled my passion for equitable, safe, and effective healthcare. Working in an outpatient chronic pain clinic exposed me to disparities in the right to care as well as the limited resources available for

reproductive health. These experiences provided me with insights into the challenges patients might experience when trying to access reproductive healthcare.

My experiences with accessing contraception and emergency contraception have further shaped my understanding of the importance of offering timely, accessible, and effective care to those seeking services. Given my professional background and my numerous encounters with pharmacists, my nursing profession has been rewarding. However, my foray into research has been eye-opening, steering my interest toward a career that integrates both clinical and research components.

The completion of my master's project marks a significant opportunity to contribute to the regulatory reform of emergency contraception and present the current status of emergency contraception in pharmacies—an opportunity for which I am sincerely grateful. Throughout my project, I consistently reflected on how my position could impact data collection and analysis. I believe that as a researcher and as a clinician I am well positioned to make recommendations about service delivery changes that are feasible and respectful of other health service professionals.

<u>Statement of contribution</u>

I successfully led both components of this study, fulfilling a vital component of the requirements for the Master of Science in Interdisciplinary Health Sciences Program at the University of Ottawa. I designed the scoping review protocol, identified the source material, conducted the charting and analysis, and led the writing of the article. In undertaking this component of my project I received guidance from my supervisor, post-doctoral fellow Dr. Anvita Dixit, and University of Ottawa librarians.

For the mystery client study, I served as the Study Coordinator for the larger ASEC project. In that capacity, I revised and refined the study instruments to ensure that they were appropriate for a Canadian survey, created French translations of the materials, oversaw data

collection and collected some data myself, and led the analysis and writing of the report. I also supervised a one-term honours student who contributed to the background research for the report and the analysis of the data. Carly Demont, a PhD student and the Volunteer Coordinator for my supervisor's research group, helped identify and manage the volunteers who worked on this study. My supervisor guided all phases of the project.

Conclusion

The regulatory journey of progestin-only emergency contraception in Canada serves as an example of sexual and reproductive health drug deregulation. The process of deregulation was complex and required a multi-pronged research, clinical service, and advocacy strategy. This journey offers lessons for how other drugs could similarly move from Schedule III to Schedule II and eventually Schedule I status. However, deregulation is not enough to ensure real-world availability and accessibility. Our findings highlight the need for continued education of and engagement with pharmacists and pharmacy staff to support the full implementation of policies designed to increase timely access to essential medications.

References

About | American Society for Emergency Contraception. (n.d.). American Society For. Retrieved December 14, 2023, from https://www.americansocietyforec.org/about

Arksey, H., & O'Malley, L. (2005). Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology*. https://doi.org/10.1080/1364557032000119616

B.C. Reg.417. (2009). Pharmacists Regulation. https://www.bclaws.gov.bc.ca/civix/document/id/loo87/loo87/28_417_2008

Black, A., Guilbert, E., Costescu, D., Dunn, S., Fisher, W., Kives, S., Mirosh, M., Norman, W., Pymar, H., Reid, R., Roy, G., Varto, H., Waddington, A., Wagner, M.-S., & Whelan, A. M. (2016). Canadian Contraception Consensus (Part 3 of 4): Chapter 8 – Progestin-only contraception. Journal of Obstetrics and Gynaecology Canada, 38(3), 279–300. https://doi.org/10.1016/j.jogc.2015.12.003

Borsella, M., & Foster, A. M. (2021). *Women's knowledge of, access to, and experiences with emergency contraception in New Brunswick*.

Borsella, M., & Foster, A. M. (2020). Exploring the Availability of Emergency Contraception in New Brunswick Pharmacies: A Mystery-Client Telephone Study. *Pharmacy*, *8*(2), Article 2. https://doi.org/10.3390/pharmacy8020076

Brogan, N. R. (2019). Exploring the Contraceptive Experiences of Adolescents Living in Rural Ontario [Thesis, Université d'Ottawa / University of Ottawa]. https://doi.org/10.20381/ruor-24098

Business Wire (2002, March 8). Application to take Plan B emergency contraception over-the-counter submitted in Canada. Business Wire, 1.

Business Wire (1997). Obstetricians recommend morning-after pill. Canadian Press Enterprises Inc.

Canadian Women's Health Network. (2005). Improving access to emergency contraception. Canadian Women's Health Network. https://books-scholarsportal-info.proxy.bib.uottawa.ca/en/read?id=/ebooks/ebooks0/gibson_cppc/2009-12-01/3/203273#page=2

Cano, J. K., & Foster, A. M. (2016). "They made me go through like weeks of appointments and everything": Documenting women's experiences seeking abortion care in Yukon territory, Canada. Contraception, 94(5), 489–495. https://doi.org/10.1016/j.contraception.2016.06.015

Chan, M., Soon, J., Schummers, L., Munro, S., Ragsdale, P., Albert, A., Fitzsimmons, B., & Renner, R. (2020). Current dispensing and practice use patterns of ulipristal acetate 30mg (Ella®), as emergency contraception in British Columbia, Canada. Journal of Obstetrics and Gynaecology Canada, 42(5), 671. https://doi.org/10.1016/j.jogc.2020.02.030

Chaumont, A., & Foster, A. M. (2017). The not so over-the-counter status of emergency contraception in Ontario: A mixed methods study with pharmacists. *FACETS*, *2*, 429–439. https://doi.org/10.1139/facets-2017-0024

Canadian Medical Association. Journal. (2005). Emergency contraception moves behind the counter. Canadian Medical Association. Journal: CMAJ, 172(7), 845, 847.

Cleland, K., Raymond, E. G., Westley, E., & Trussell, J. (2014). Emergency contraception review: Evidence-based recommendations for clinicians. *Clinical Obstetrics and Gynecology*, *57*(4), 741–750. https://doi.org/10.1097/GRF.0000000000000056

Cohen, M. M., Dunn, S., Cockerill, R., & Brown, T. E. (2004). Using a secret shopper to evaluate pharmacist provision of emergency contraception: Satisfaction levels high, with privacy a concern. *Canadian Pharmacists Journal,* 137(1), 28–33.

Cook, R., Dickens, B., & Erdman, J. N. (2006). *Emergency contraception, abortion and evidence-based law*. file:///Users/emiliefriesen/Downloads/SSRN-id944810_stamped%20(1).pdf

Covidence. (2022). *Covidence systematic review software.* Melbourne, Australia. Veritas health innovation. Available at www.covidence.org.

Creinin, M. D., & Danielsson, K. G. (2009). Medical Abortion in Early Pregnancy. In Management of Unintended and Abnormal Pregnancy (pp. 111–134). John Wiley & Sons, Ltd. https://doi.org/10.1002/9781444313031.ch9

CWHN. (2005). Improving access to emergency contraception. https://books-scholarsportal-info.proxy.bib.uottawa.ca/en/read?id=/ebooks/ebooks0/gibson_cppc/2009-12-01/3/203273#page=1

Dailard, C. (1999). Abortion in context: United States and worldwide. *Issues in Brief (Alan Guttmacher Institute)*, *1*, 1–6.

Demont, C., Dixit, A., & Foster, A. M. (2023). Later gestational age abortion in Canada: A scoping review. *The Canadian Journal of Human Sexuality*, *32*(1), 51–63. https://doi.org/10.3138/cjhs.2022-0046

Dunn, S., Brown, T. E., & Alldred, J. (2008). Availability of emergency contraception after its deregulation from prescription-only status: A survey of Ontario pharmacies. Canadian Medical Association. Journal: CMAJ, 178(4), 423–424.

Dunn, S., Guilbert, E., Lefebvre, G., Allaire, C., Arneja, J., Birch, C., Fortier, M., Jeffrey, J., Vilos, G., Wagner, M. S., Grant, L., Beaudoin, F., Cherniak, D., Pellizzari, R., Sadownik, L., Saraf-Dhar, R., Turnbull, V., & Clinical Practice Gyneacology and Social Sexual Issues Committees, Society of Obstetricians and Gyneacologists of Canada (SOGC) (2003a). Emergency contraception. Journal of obstetrics and gynaecology Canada: JOGC, 25(8), 673–690.

Dunn, S., Brown, T. E. R., Cohen, M. M., Cockerill, R., Wichman, K., Weir, N., & Pancham, A. (2003b). Pharmacy provision of emergency contraception: The Ontario emergency contraception pilot project. Journal of Obstetrics and Gynaecology Canada: JOGC, 25(11), 923–930. https://doi.org/10.1016/s1701-2163(16)30240-7

Ederman, J. N. (2012). *Canada: Competing Frames of Access and Authority*. Palgrave Macmillan. http://ebookcentral.proquest.com/lib/ottawa/detail.action?docID=912248

Erdman, & Cook, R. J. (2016). Protecting fairness in women's health: The case of emergency contraception. In Just Medicare. University of Toronto Press: Toronto; pp 137-167.

Éditeur officiel du Québec. (2011). *LQ 2011, c 37 | Loi modifiant la Loi sur la pharmacie*. CanLII. https://www.canlii.org/fr/qc/legis/loisa/lq-2011-c-37/121743/lq-2011-c-37.html

Eggertson, L. (2001). Abortion services in Canada: A patchwork quilt with many holes. Canadian Medical Association. Journal: CMAJ, 164(6), 847–849.

Eggertson, L. (2006a). Manitoba pharmacists' association clarifies Plan B regulations. Canadian Medical Association. Journal: CMAJ.

Eggertson, L. (2006b). Ontario pharmacists drop Plan B screening form. Can Med Assoc.

Eggertson, L. (2008). Plan B comes out from behind the counter. *CMAJ: Canadian Medical Association Journal = Journal de l'Association Medicale Canadienne*, *178*(13), 1645–1646. https://doi.org/10.1503/cmaj.080809

Foster, A. M., LaRoche, K. J., El-Haddad, J., DeGroot, L., & El-Mowafi, I. M. (2017). "If I ever did have a daughter, I wouldn't raise her in New Brunswick:" exploring women's experiences obtaining abortion care before and after policy reform. *Contraception*, *95*(5), 477–484. https://doi.org/10.1016/j.contraception.2017.02.016

Foster, A., & Wynn, L. (2012). *Emergency Contraception: The Story of a Global Reproductive Health Technology*. Palgrave Macmillan. http://ebookcentral.proquest.com/lib/ottawa/detail.action?docID=912248

Flood, C. M., Denham, R. D., & Flood, C. M. F. (2006). Just Medicare: What's In, What's Out, How We Decide. UTP: University of Toronto Press. https://canadacommons.ca/artifacts/1872733/just-medicare/2621654/

Ganatra, B. (2015). Health worker roles in safe abortion care and post-abortion contraception. The Lancet Global Health, 3(9), e512–e513. https://doi.org/10.1016/S2214-109X(15)00145-X

Gatter, M., Cleland, K., & Nucatola, D. L. (2015). Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days. Contraception, 91(4), 269–273. https://doi.org/10.1016/j.contraception.2015.01.005

Government of Canada. (2004a). Government of Canada. Canada.ca. https://www.canada.ca/en/news/archive/2004/05/government-canada-proposes-access-morning-after-pill-without-prescription.html

Government of Canada. (2004b). Canada Gazette Part I. 138(21), 55.

Government of Canada, I. A. P. on R. E. (2022). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)*. https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

Grimes, D., Hertzen, H. von, Piaggio, G., & Look, P. F. A. V. (1998). Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *The Lancet*, *352*(9126), 428–433. https://doi.org/10.1016/S0140-6736(98)05145-9

Harris, J. (2019). *National Capital Region | The Canadian Encyclopedia*. https://www.thecanadianencyclopedia.ca/en/article/national-capital-region

Harper, C. C., Cheong, M., Rocca, C. H., Darney, P. D., & Raine, T. R. (2005). The Effect of Increased Access to Emergency Contraception Among Young Adolescents. *Obstetrics & Gynecology*, *106*(3), 483. https://doi.org/10.1097/01.AOG.0000174000.37962.a1

Hope Spencer, M. (2001). Expanding access to emergency contraceptive pills. *Canadian Family Physician*, *47*(OCT.), 2168.

Hukku, S., Gauthier-Beaupré, A., Fortier, E., Doci, F., Veillet-Lemay, G., Gure, F., LaRoche, K., & Foster, A. (2018). Exploring young adults' knowledge of and experiences with emergency contraception in Ontario, Canada: A mixed-methods study. Contraception, 98(4), 359. https://doi.org/10.1016/j.contraception.2018.07.093

Kermode-Scott, B. (2008). Canada's drug advisory committee says emergency contraception should be available over the counter. British Medical Journal Publishing Group.

Langille, D. B., Allen, M., & Whelan, A. M. (2012). Emergency contraception: Knowledge and attitudes of Nova Scotian family physicians. *Canadian Family Physician*, 58(5), 548–554.

LaRoche, K. J., & Foster, A. M. (2020). "It gives you autonomy over your own choices": A qualitative study of Canadian abortion patients' experiences with mifepristone and misoprostol. Contraception, 102(1), 61–65.

Leung, V. W. Y., Soon, J. A., & Levine, M. (2008). Emergency contraception update: A Canadian perspective. Clinical Pharmacology & Therapeutics, 83(1), 177–180.

Levac, D., Colquhoun, H. & O'Brien, K. (2010). Scoping studies: Advancing methodology. Implementation Science, 5(69), 1-9.

Lynas, K. (2005). Pharmacists to provide ECP without doctor's prescription. Canadian Pharmacists Journal, 138(4), 13.

Lynd, L. D., Taylor, J., Dobson, R., & Willison, D. J. (2005). Prescription to over-the-counter deregulation in Canada: Are we ready for it, or do we need to be? Canadian Medical Association. Journal: CMAJ, 173(7), 775–777.

Marketwire. (2008). Pharmacists disappointed by emergency contraception decision. Marketwire. https://www.proquest.com/docview/447794301/abstract/4BD66C646ED14D6BPQ/1?parentSessionId=fFncVPaFGfc7KFqMfOImzpcXRf1o5q7qrDjaFbQv9oI%3D&#

McCutcheon, G., Farnham, J., & Cantin, L. (2005). Emergency contraception. Canadian Medical Association. Journal: CMAJ, 173(6), 575.

Moseson, H., Jayaweera, R., Raifman, S., Keefe-Oates, B., Filippa, S., Motana, R., Egwuatu, I., Grosso, B., Kristianingrum, I., Nmezi, S., Zurbriggen, R., & Gerdts, C. (2020). Self-managed medication abortion outcomes: Results from a prospective pilot study. *Reproductive Health*, *17*(1), 164. https://doi.org/10.1186/s12978-020-01016-4

Munn, Z., Peters, M. D. J., Stern, C., Tufanaru, C., McArthur, A., & Aromataris, E. (2018). Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Medical Research Methodology*, *18*(1). https://doi.org/10.1186/s12874-018-0611-x

Murray, G., & Todkill, A. M. (2006). Privacy issues and Plan B: The Canadian Pharmacists Association responds. Canadian Medical Association. Journal: CMAJ, 174(1), 64–66.

Murray, G., & Todkill, A. M. (2006). Privacy issues and Plan B: The Canadian Pharmacists Association responds. CMAJ: Canadian Medical Association Journal, 174(1), 64–66.

NAPRA (2017) *National Drug Scheduling Factors Schedule I - NAPRA*, *National Drug Scheduling Factors Schedule I.* Available at: https://www.napra.ca/wp-content/uploads/2022/08/NAPRA-NDSAC-Scheduling-Factors-September-2017.pdf

Nguyen, T. (2005). Plan B - like it or not. CPJ. Canadian Pharmaceutical Journal, 138(4), 12.

Osmond, B. (2000). Access to the morning-after pill in BC. Canadian Medical Association. Journal: CMAJ, 162(11), 1554–1554.

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., & Brennan, S. E. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. International Journal of Surgery, 88, 105906.

Pancham, A., & Dunn, S. (2007). Emergency contraception in Canada: An overview and recent developments. Canadian Journal of Human Sexuality, 16(3/4), 129.

Praditpan, P., Hamouie, A., Basaraba, C. N., Nandakumar, R., Cremers, S., Davis, A. R., & Westhoff, C. L. (2017). Pharmacokinetics of levonorgestrel and ulipristal acetate emergency contraception in women with normal and obese body mass index. *Contraception*, *95*(5), 464–469. https://doi.org/10.1016/j.contraception.2017.01.004

PRISMA. (2021). PRISMA for scoping reviews. Retrieved from http://www.prisma-statement.org/Extensions/ScopingReviews

Rhyno, C. (2001a). Emergency contraception: Supply in demand. Canadian Pharmacists Journal, 134(10), 15.

Rhyno, C. (2001b). Switching to Plan B: While the makers of Canada’s first emergency contraception pill are abandoning the market because of slow sales, Saskatchewan is poised to become one of the first to approve another product, plan B, for sale from pharmacies without a doctor’s prescription. Canadian Pharmacists Journal, 134(2), 19.

Sabourin, J. N., & Burnett, M. (2012). A Review of Therapeutic Abortions and Related Areas of Concern in Canada. Journal of Obstetrics and Gynaecology Canada, 34(6), 532–542. https://doi.org/10.1016/S1701-2163(16)35269-0

Schiappacasse, V., & Diaz, S. (2006). Access to emergency contraception. International Journal of Gynecology and Obstetrics, 94(3), 301–309. https://doi.org/10.1016/j.ijgo.2006.04.017

Sibbald, B. (1999). With teen pregnancies skyrocketing, ob/gyns seek support for nonprescription “morning-after pill”. Canadian Medical Association. Journal: CMAJ, 161(7), 855.

Sibbald, B. (2000). Despite some opposition, BC pharmacists to dispense morning-after pill without prescription. Canadian Medical Association. Journal: CMAJ

Sibbald, B. (2001). Over-the-counter emergency contraception available soon across country? *CMAJ: Canadian Medical Association Journal*, *164*(6), 849.

Sibbald, B. (2005). Nonprescription status for emergency contraception. Canadian Medical Association. Journal: CMAJ, 172(7), 861–862.

Shoveller, J., Chabot, C., Soon, J. A., & Levine, M. (2007). Identifying Barriers to Emergency Contraception Use Among Young Women from Various Sociocultural Groups in British Columbia, Canada. Perspectives on Sexual and Reproductive Health, 39(1), 13–20. https://doi.org/10.1363/3901307

Smith, D. (2020, September 28). Funding and abortion access in New Brunswick. The National CBA/ABC. https://nationalmagazine.ca/en-ca/articles/law/hot-topics-in-law/2020/abortion-access-in-new-brunswick

Soon, J. A., Levine, M., Ensom, M. H. H., Fielding, D. W., Gardner, J. S., & Edmondson, H. M. (2002). The developing role of pharmacists in patient access to emergency

contraception. Disease Management and Health Outcomes, 10(10), 601–611. https://doi.org/10.2165/00115677-200210100-00001

Soon, J. A., Levine, M., Osmond, B. L., Ensom, M. H. H., & Fielding, D. W. (2004). Provision of Emergency Contraceptives by Pharmacists: British Columbia Experience a Template for other Provinces. Canadian Pharmacists Journal / Revue Des Pharmaciens Du Canada, 137(6), 23–29. https://doi.org/10.1177/171516350413700605

Soon, J. A., Levine, M., Osmond, B. L., Ensom, M. H. H., & Fielding, D. W. (2005). Effects of making emergency contraception available without a physician's prescription: A population-based study. CMAJ, 172(7), 878–883. https://doi.org/10.1503/cmaj.045019

Soper, K., & Di Meglio, G. (2020). Accessibility of emergency contraception for adolescents in Quebec community pharmacies. *Paediatrics & Child Health*, *25*(6), 385–388. https://doi.org/10.1093/pch/pxz109

Ti AJ, et al. (2020). Effectiveness and safety of extending intrauterine device duration: A systematic review. American Journal of Obstetrics and Gynecology, 223(1): 24–35.e3. DOI: 10.1016/j.ajog.2020.01.014.

Tricco, A. C., Lillie, E., Zarin, W., O'Brien, K. K., Colquhoun, H., Levac, D., Moher, D., Peters, M. D. J., Horsley, T., Weeks, L., Hempel, S., Akl, E. A., Chang, C., McGowan, J., Stewart, L., Hartling, L., Aldcroft, A., Wilson, M. G., Garritty, C., … Straus, S. E. (2018). PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. Annals of Internal Medicine, 169(7), 467–473. https://doi.org/10.7326/M18-0850

Trussell, J. (2012). Emergency contraception: Hopes and realities. In Emergency contraception: The story of a global reproductive health technology, Foster, A. M., & Wynn, L. L. (Eds.). Palgrave Macmillan: New York; pp 19-35. https://doi.org/10.1057/9781137016485

Trussell, J., Raymond, E. G., & Cleland, K. (2014). Emergency contraception: A last chance to prevent unintended pregnancy. *Contemporary Readings in Law and Social Justice*, *6*(2), 7–39.

Trussell, J., Rodríguez, G., & Ellertson, C. (1998). New estimates of the effectiveness of the Yuzpe regimen of emergency contraception. *Contraception*, *57*(6), 363–369. https://doi.org/10.1016/S0010-7824(98)00042-0

Vogel, L. (2015). Rethink weight limits on morning-after pill. *CMAJ: Canadian Medical Association Journal*, *187*(10), 719–721. https://doi.org/10.1503/cmaj.109-5098

Whelan, A. M., Langille, D. B., White, S. J. K., Asbridge, M., & Flowerdew, G. (2011). Knowledge of, beliefs about, and perceived barriers to the use of the emergency contraception pill among women aged 18-51 in Nova Scotia. Pharmacy Practice, 9(3), 148–155.

Williams, B. N., Jauk, V. C., Szychowski, J. M., & Arbuckle, J. L. (2021). Adolescent emergency contraception usage, knowledge, and perception. *Contraception*, *103*(5), 361–366. https://doi.org/10.1016/j.contraception.2021.01.003

Winikoff, B., Hassoun, D., & Bracken, H. (2011). Introduction and provision of medical abortion: A tale of two countries in which technology is necessary but not sufficient. Contraception, 83(4), 322–329. https://doi.org/10.1016/j.contraception.2010.08.009

World Health Organization. (2021). *Emergency contraception*. https://www.who.int/news-room/fact-sheets/detail/emergency-contraception

Wynn, L. I., Erdman, J. N., Foster, A. M., & Trussell, J. (2007a). Harm Reduction or Women's Rights? Debating Access to Emergency Contraceptive Pills in Canada and the United States. *Studies in Family Planning*, *38*(4), 253–267. https://doi.org/10.1111/j.1728-4465.2007.00138.x

Wynn, L. I., Erdman, J. N., Foster, A. M., & Trussell, J. (2007b). Harm Reduction or Women's Rights? Debating Access to Emergency Contraceptive Pills in Canada and the United States. *Studies in Family Planning*, *38*(4), 253–267. https://doi.org/10.1111/j.1728-4465.2007.00138.x

Yuksel, N., Schindel, T., Siyam, T., & Hocevar, S. (2011). Pharmacists' beliefs about Plan B as an over-the-counter product. Canadian Pharmacists Journal, 144(5), e40.