

The not so over-the-counter status of emergency contraception in Ontario: A mixed methods study with pharmacists

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Abstract

Introduction: In Canada, the progestin-only dedicated pill is the most widely used method of emergency contraception (EC). This method gained over-the-counter status in Ontario in 2008. Our mixed methods study explored the progestin-only EC knowledge, attitudes, and provision practices of Ontario pharmacists.

Methods: From June 2015 to October 2015, we collected 198 mailed surveys from Ontarian pharmacy representatives and conducted 17 in-depth interviews with a subset of respondents. We analyzed these data using descriptive statistics and for content and themes.

Results: Results from our English/French bilingual survey indicate that respondents' knowledge is generally accurate, but confusion persists about the mechanism of action and the number of times the drug can be used in one menstrual cycle. Nearly half (49%) of our survey respondents indicated that progestin-only EC pills are only available behind the counter. Interviewees strongly supported the introduction and promotion of more effective methods of EC in Ontario.

Conclusion: Continuing education focusing on both the regulatory status of progestin-only EC and information about the medication appears warranted. Health Canada's recent approval of ulipristal acetate for use as a post-coital contraceptive may provide a window of opportunity for engaging with health service providers, including pharmacists, about all available modalities of EC in Canada.

Key words: emergency contraception, levonorgestrel, Canada, reproductive health



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

Editor: James R. Woodgett

Received: March 5, 2017

Accepted: March 29, 2017

Published: May 16, 2017

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Published by: Canadian Science Publishing

Introduction

Emergency contraceptives are medications or devices that are used to prevent pregnancy after unprotected or under-protected sex. In Canada, the progestin-only dedicated pill, the Copper-T intrauterine device (IUD), and the Yupze method have long been available as methods of emergency contraception (EC). In addition, in 2015, Health Canada approved ulipristal acetate (UPA) for use as a post-coital contraceptive. However, for years the most widely used method of EC by Canadian women has been the progestin-only EC pill ([Soon et al. 2005](#)). A body of evidence shows that when used within 120 h of a sexual event, a single 1.5 mg dose of levonorgestrel can reduce the risk of pregnancy by up to 89% ([Trussell 2012](#)). Because the primary mechanism of action of progestin-only EC is to delay or inhibit ovulation, the medication is more effective when taken as soon after sex as possible ([Trussell 2012](#)).

In Ontario, progestin-only EC was first approved as a Schedule I drug requiring a prescription in 2000. In 2005, a regulatory change resulted in progestin-only EC moving to Schedule II status, such that a prescription was no longer required ([Canadian Medical Association Journal 2005](#)). This represented an important step in increasing timely access to the medication because women were then able to procure EC directly from pharmacists. However, a consultation with a pharmacist was still required. In 2008, the National Drug Scheduling Advisory Committee recommended the deregulation of progestin-only EC to a Schedule III drug, moving it from behind-the-counter (BTC) status to over-the-counter (OTC) status ([Eggertson 2008](#)). Thus, for almost a decade, women in Ontario have not been required to interact with a pharmacist to obtain progestin-only EC. As of 2016, three brands of progestin-only EC were available: Plan B® (the most widely used and well known) and two generic brands (NextChoice® and Option 2®). In response to recent studies suggesting that progestin-only EC may be less or not at all effective when used by heavier women ([Glasier et al. 2011](#); [Kapp et al. 2015](#); [Gemzell-Danielsson et al. 2015](#)), in 2014, Health Canada issued a warning stating that progestin-only EC may be less effective in women weighing 165 pounds or more and ineffective in women weighing over 176 pounds ([Eggertson 2014](#)). Health Canada subsequently requested that the labels for all progestin-only EC products in Canada incorporate this warning ([Health Canada 2014](#)).

As patient-oriented health care professionals, pharmacists are available and accessible to their communities and have long played a critical role in EC service delivery. However, the scientific literature on Canadian pharmacists' EC knowledge and attitudes is limited. In addition, no study has been undertaken in Ontario since the last regulatory status change to determine current provision practices or since the weight advisory for progestin-only EC went into effect. Through a mixed methods study, we aimed to assess the knowledge, attitudes, and practice patterns of community pharmacists in Ontario with respect to all modalities of EC. In this paper, we focus on the findings that are specifically related to progestin-only EC pills.

Methods

Study design and data collection

Our study had two components: a mailed survey to Ontario pharmacists and in-depth interviews with a subset of survey respondents. With permission, we based our selection of pharmacies and the design of our survey instrument on a study conducted by [Dunn et al. \(2008\)](#) in the wake of the switch to BTC status.

We used a database from the Ontario College of Pharmacists to obtain our sample of community-based retail pharmacies, of which there were 4232 listed at the time of the study. We used a stratified random selection process to identify our sample and intentionally over-sampled independent pharmacies, pharmacies in rural areas, and pharmacies located in Franco-Ontarian communities. We initially sent surveys to 1428 pharmacies in June 2015; after accounting for closed pharmacies and inaccurate addresses, we ultimately surveyed 1396 pharmacies.

We contacted pharmacies four times over the course of the study period. The first contact included a bilingual (English/French) survey package with an instruction letter, the survey instrument, a stamped return envelope, a key informant interview response card, and a response card to participate in a draw for a \$100 CAD gift card (one per 100 respondents). We sent non-respondents a reminder postcard after 1 month. Continued non-respondents received a second survey package and a final reminder postcard 3 and 4 months after the initial mailing, respectively. We included all surveys received before the end of calendar year 2015 in our analysis.

Our questionnaire included four domains. The first section focused on demographic questions about the respondent, pharmacy, and catchment area. The second section contained a series of close-ended multiple choice and knowledge assessment questions related to different modalities of EC.

The penultimate section asked the respondent a series of questions about current progestin-only EC provision practices. The final section explored respondents' attitudes toward and interest in continuing education efforts and explored ways in which EC service delivery could be improved. We also provided participants with a free response space to comment on EC-related issues. Our cover letter asked participants not to consult resources or other members of the pharmacy team when completing the survey. We piloted the questionnaire with a convenience sample of 10 Anglophone and three Francophone pharmacists in May 2015; feedback from these early interactions allowed us to finalize the instrument and translation and demonstrated that completing the survey required about 20 min.

We invited respondents to participate in a telephone/Skype follow-up interview to discuss issues related to service delivery in depth. A Master's student (AC) in Health Sciences at the University of Ottawa conducted all English and French interviews, after receiving training from her supervisor (AMF), a medical doctor and medical anthropologist with extensive experience leading qualitative EC-related studies. We used an interview guide developed specifically for this study that explored the participant's background, current practices, and reflections on the introduction of UPA and use of the IUD as EC. We concluded the interview with a discussion of avenues for improving EC access and engaging with pharmacists in Ontario. With permission, we audio recorded all interviews, which averaged about 30 min each, and offered all participants a \$20 CAD gift certificate. AC took notes during and wrote formal memos immediately after each interaction.

Data analysis

We entered the survey responses into FluidSurveys and, after conducting an audit, exported our data to IBM SPSS 23.0 for statistical analysis. We analyzed our data using descriptive statistics, χ^2 analysis, and Fisher's exact test to detect regional differences and differences by pharmacy type. We analyzed open-ended questions for content and themes.

We used an iterative process to analyze our interviews for content and themes; this process began during data collection. AC or a study volunteer transcribed interviews verbatim, and we used ATLAS.ti (atlasti.com/) to manage our data. We developed an initial codebook based on study questions and expected responses, and added codes and categories that emerged during the analytic process. Regular meetings between AC, the primary coder, and AMF guided our interpretation of the findings. In the final analytic phase, we combined the results of both components of the mixed methods study paying special attention to concordance and discordance.

Ethical considerations

We received ethics approval from the Research Ethics Boards at the University of Ottawa (File# H03-14-20 and File# 02-15-12). Throughout this manuscript, we have redacted or masked all personally identifying information about individual pharmacists and their pharmacies. We have translated all French-language responses from both the survey and the interview components to English.

Results

Description of participants and their pharmacies

We received 198 surveys (response rate of 14.2%); all but two respondents completed the survey in English. The majority of our survey respondents were from independent (39.1%) or chain (30.5%) pharmacies, and close to half of these pharmacies were located in the southern region of the province (46.6%). Nearly two thirds of respondent pharmacies were located in urban areas (65.0%) and all were open on weekdays; 82.3% of pharmacies were open on Sundays. One out of 10 respondents reported that the pharmacy was located more than 15 min drive from another pharmacy. We provide detailed information about the characteristics of these pharmacies in [Table 1](#).

Table 1. Characteristics of the pharmacies reported on by survey respondents ($n = 198$).

	<i>n (%)</i>
Type of pharmacy	
Independent	77 (39.1)
Chain	60 (30.5)
Banner	51 (25.9)
Other/no response	10 (5.07)
Regional location of the pharmacy	
East	34 (17.4)
Central	41 (21.0)
South	91 (46.7)
North	29 (14.9)
No response	3 (1.51)
Area location of the pharmacy	
Urban	128 (65.0)
Rural	69 (35.0)
No response	1 (0.5)
Another pharmacy located within a 15 min drive	
Yes	180 (90.9)
No	18 (8.6)
No response	1 (0.5)
Store hours^a	
Weekdays	198 (100)
Saturdays	189 (95.5)
Sundays	163 (82.3)
Principal languages spoken by pharmacy staff^a	
English	195 (98.5)
French	34 (17.2)
Arabic	28 (14.1)
Chinese	27 (13.6)
Hindi	12 (6.06)
Punjabi	7 (3.53)
Spanish	5 (2.52)
Other/no response	34 (17.2)
Principal languages spoken by clientele^a	
English	191 (97.0)

(continued)

Table 1. (concluded)

	<i>n</i> (%)
French	37 (18.8)
Arabic	17 (8.60)
Chinese	23 (11.7)
Hindi	18 (9.13)
Punjabi	12 (6.09)
Spanish	7 (3.55)
Other/no response	27 (13.7)

^aDoes not total 100% as respondents could select multiple responses.

We conducted 17 in-depth interviews with pharmacists practicing in Ontario; we completed 15 in English and two in French. Our interviewees worked in independent ($n = 7$), chain ($n = 3$), and banner ($n = 7$) pharmacies, and 12 self-identified as women.¹ Almost all interviewees worked in pharmacies located in urban areas ($n = 15$) and in the central and south ($n = 11$) regions of the province.

Ontario pharmacists' knowledge of progestin-only EC

Overall, survey respondents demonstrated accurate knowledge of progestin-only EC. The majority of our participants (68.5%) correctly identified 1.5 mg of levonorgestrel taken as one dose as the evidence-based regimen and cited the most common side effects as nausea (96.9%), vomiting (76.4%), and inter-menstrual bleeding (53.3%). Three quarters of respondents reported that progestin-only EC must be taken within 72 h ($n = 145$, 75.1%) or within 120 h ($n = 29$, 15.0%), and 72.8% ($n = 142$) correctly indicated that efficacy decreases when the drug is taken more than 24 h after intercourse.

However, our survey results indicated that confusion persists surrounding the primary mechanism of action and how to manage side effects. Fully three quarters of our participants ($n = 150$, 77.7%) incorrectly indicated on a true/false question that progestin-only EC's primary mechanism of action is to inhibit implantation, and nearly half ($n = 91$, 48.4%) reported that progestin-only EC should be taken in conjunction with a meal, a recommendation that is not evidence based. In addition, 26.5% ($n = 50$) of our respondents indicated that there is a limit to the number of times that a woman can take progestin-only EC in one menstrual cycle.

Consistent with Health Canada's warning, 70.5% ($n = 134$) of our participants reported that the efficacy of progestin-only EC is lower in women weighing 75 kg or more. Several of our in-depth interview participants also discussed the weight efficacy issue and explained that they routinely inform patients of this risk. As explained by a Francophone pharmacist working at a pharmacy in the eastern region of the province:

Guidelines and studies are not yet clear enough for me to decide whether I should provide [progestin-only EC] or not. If an 80 kg women does not want to become pregnant I do not

¹A banner pharmacy is independently owned and operated, but for a fee affiliates with a central office and uses a recognized name.

want to be the cause [of an unwanted pregnancy]. There are few side effects, no down sides [to progestin-only EC] . . . we can still provide it but recommend women consult with a doctor later on. But this gives lots of women a false sense of security.

Progestin-only EC availability

Almost all survey respondents ($n = 177$, 93.2%) reported having progestin-only EC in stock at the time of the survey; Plan B®, Next Choice®, and Option 2® were carried by 97%, 26%, and 25% of these pharmacies, respectively. Of those pharmacies that carried a progestin-only EC product, the reported price ranged from \$20 CAD to \$60 CAD; consistent with drug pricing in general, the price of the brand product was generally higher than the price of generics. We did not detect statistically significant differences in price based on region or pharmacy type. Those pharmacies without progestin-only EC in stock related this to patient demographics, particularly elderly patient populations. However, most respondents ($n = 179$, 94.2%) indicated that the pharmacy receives requests for EC from patients, from less than 1 to more than 50 each month; the majority of respondents ($n = 145$, 83.8%) reported receiving 1–5 requests per month.

Despite the long-standing OTC regulatory status of progestin-only EC in Ontario, about half of our sample reported carrying at least one brand of progestin-only EC OTC ($n = 91$, 51.4%), and the other half reported carrying at least one progestin-only EC product BTC ($n = 85$, 48.6%). Eleven respondents (6.25%) reported having products on both the main shelf and behind the pharmaceutical counter. Among our interviewees, only 4 of 17 carried all progestin-only EC products OTC. There was no difference in the placement between regions and all chain pharmacies reported carrying at least one product BTC.

The interviews gave us insight into why pharmacists continue to keep the medication BTC. The majority of our interviewees ($n = 12$) kept progestin-only EC BTC to counsel patients and (or) create an opportunity for consultation. As explained by an Anglophone pharmacist working in an independent pharmacy in the southern region:

I think there is pharmacist intervention needed. I always make sure that the patient present is the one that, like the female patient is presenting to the pharmacy to ask for it. And that there is [specific] advice and learning appropriate for the patient. All of that is not done when it's over-the-counter. And there is a need to get patient details . . . I just want to make sure that this is going to be effective and safe for them.

Interviewees also indicated that concerns about theft, particularly of the more expensive branded product, and the absence of space factored into placement decision-making. Two of our interviewees kept the medication BTC because of a lack of understanding of the current regulations.

Progestin-only provision practices

In general, survey respondents reported that pharmacies provide a dedicated space for consultation ($n = 178$, 93.7%) and about a third ($n = 70$, 36.8%) sometimes use a screening or counseling tool during an EC-related consultation. Interview participants reported providing those seeking progestin-only EC with information and also asking a range of questions. Most of the EC information centered on side effects, regimen, future pregnancy prevention, and weight. Questions typically focused on the timing of intercourse, previous use of EC, and whether or not the woman wanted additional information. As noted by one Anglophone pharmacist working in the eastern region in a chain pharmacy:

The most important [question] is when did it happen? You want to check if they're eligible or not, sometimes they don't know and they come and then you're like "whoah don't buy it," so I always ask when for sure.

Almost all of our interviewees ($n = 16$) felt that obtaining EC should include a mandatory standardized consultation with a pharmacist.

About a quarter of our survey participants ($n = 45$, 23.9%) reported that they had, at least on occasion, not provided progestin-only EC to someone who had requested it. Survey participants indicated their primary reasons as (1) not having the medication in stock ($n = 16$, 37.2%); (2) identifying that the unprotected intercourse occurred outside of the timeframe for use ($n = 14$, 32.6%); (3) confirming or suspecting a pregnancy ($n = 13$, 12.6%); (4) the patient not presenting in person ($n = 10$, 23.3%); or (5) the patient having contraindications or drug interactions ($n = 7$, 16.3%). None of the interviewees ever refused to provide the medication to a patient, but five had referred women to other reproductive health care providers. One of our Francophone participants from northern Ontario explained, "One of our patients was coming into the pharmacy almost once a month to get a Plan B®. So I referred her to [the] Health Unit for a birth control pill".

Most survey respondents ($n = 134$, 70.9%) reported that their comfort in providing EC was on par with providing other medications; only 16.4% ($n = 31$) reported feeling less comfortable providing information about EC. Although most survey respondents reported having never obtained continuing education about EC, the overwhelming majority ($n = 166$, 86%) expressed interest in receiving information about EC in the future. Participants in our interviews were enthusiastic about the possibility of engaging in continuing education around EC. One interviewee working at a chain pharmacy in the southern region of Ontario highlighted:

I think we did not cover [EC] well at all in school. As a recent grad, I remember exactly what happened. [EC] is something I've learned through practice and through different continuing events or word around the pharmacy community. I am sure that a lot of us would join [an EC continuing education course].

Discussion

General implications

A number of studies in North America have indicated that BTC status poses a barrier to timely access to progestin-only EC (Cohen et al. 2003; Erdman 2012; Wynn and Foster 2012). Furthermore, requiring a pharmacist consultation to obtain progestin-only EC subjects women to intrusive questions, raises privacy concerns, creates opportunities for pharmacists to deny women services, and increases costs (Eggertson and Sibbald 2005; Wynn et al. 2007; Eggertson 2008; Erdman 2012). Finally, keeping the product BTC creates a barrier for men who wish to purchase progestin-only EC on behalf of a friend or partner. These dynamics have shaped global and Canadian advocacy efforts to deregulate progestin-only EC (Erdman 2012; Foster and Wynn 2012).

Our results suggest that in stock availability of progestin-only EC remains comparable with the findings of Dunn et al. (2008). However, despite the regulatory change to OTC status that occurred subsequent to that study, nearly half of our survey participants reportedly carry at least one progestin-only product BTC. Circulating a reminder about progestin-only EC's OTC status through a trusted source, such as the Canadian Pharmacist's Letter, could address persistent confusion about the drug's regulatory status and appears warranted.

However, Canadian pharmacists have been long-standing advocates of BTC status (Eggertson 2008; Erdman 2012). Indeed, our interviews highlighted that for many pharmacists, the decision to carry EC BTC is not based in misinformation about the regulatory status but rather in a belief that a consultation is necessary and valuable. The pharmacists interviewed for the study reported that these consultations benefitted women, especially with respect to determining eligibility for use; our interviewees did not express concern that these consultations might be perceived as intrusive or could create barriers to seeking care. Some pharmacists appear to be ignoring the regulatory status of progestin-only EC and effectively imposing BTC status on the drug, a dynamic that professional pharmacy associations may want to explore further.

Whether pharmacists in Ontario are requiring consultations or simply providing information about progestin-only EC when those who are procuring the drug have questions, it is essential that health service professionals provide evidence-based information. Yet our results demonstrate that pharmacists' knowledge continues to be incorrect or incomplete with respect to the mechanism of action and the management of side effects. For example, routinely advising a patient to take EC in conjunction with an anti-emetic and (or) food is not evidence based (Raymond et al. 2000; Trussell 2012) and may increase the overall cost of treatment. Thus, developing continuing education resources for pharmacists, and educational resources that could be used by pharmacists in training, may address the existing gaps in knowledge.

As of the end of 2016, Canada was the only country in the world that had a formal warning about the association between weight and efficacy on the label of progestin-only EC products. Indeed, in 2014, the European Medicines Agency (EMA) retracted its original decision to include information about the weight efficacy issue from progestin-only EC product labels (EMA 2014). This has undoubtedly caused confusion among health care providers and anecdotal evidence suggests that provider practices in Canada are inconsistent (Eggertson 2014). Our findings further confirm that pharmacists have operationalized this label change in different ways. Black and Guilbert (2015) recently issued recommendations to address this issue, and our results suggest that the dissemination of evidence-based guidelines about the relationship between efficacy and weight, and a reminder to pharmacists that as an OTC product all people should be able to purchase the medication, is a priority.

Finally, the recent introduction of UPA into the Canadian health system for post-coital pregnancy prevention offers an opportunity to engage in discussion with both health service professionals and the public about all EC modalities. This is especially important given the different regulatory statuses that UPA (prescription required as of early 2017) and progestin-only EC (OTC) have and will likely continue to have in the immediate future. Developing Canada-specific educational resources for both providers and potential users could facilitate efforts to expand access to a full range of post-coital contraceptive methods.

Limitations

Despite four contacts, the response rate to our survey was low (less than 15%), and thus, our 198 respondent pharmacies represent less than 5% of retail pharmacies in Ontario. This necessarily limits the generalizability of our findings, which are best characterized as exploratory. Furthermore, we received very few responses from pharmacies in language minority communities. Future research that focuses specifically on this population should be prioritized. Although we instructed participants not to consult reference material when taking the survey, some participants may have looked up answers thus resulting in elevated levels of knowledge and a skew toward the best practices.

Conclusion

Health Canada's recent approval of ulipristal acetate for use as a post-coital contraceptive may provide a window of opportunity for engaging with health service providers, including pharmacists, about all modalities of EC available in Canada. The findings from our study suggest that continuing education efforts that focus on both the regulatory status of progestin-only EC and information about the medication are warranted and would be welcomed by retail pharmacists in Ontario.

Acknowledgements

Andréanne Chaumont received a Queen Elizabeth II Graduate Scholarship in Science and Technology and several grants from the University of Ottawa to support this project. Dr. Foster's 2011–2016 Endowed Chair in Women's Health Research was funded by the Ontario Ministry of Health and Long-Term Care and the funding attached to her Chair covered the costs associated with this study. We are also grateful to the Society of Family Planning for its support of Dr. Foster's mentorship activities. We would like to thank Drs. Raywat Deonandan and Karen Phillips for their feedback during various phases of this project and Dr. Sheila Dunn for providing us with her survey instrument. We are also grateful to the team of volunteers for their efforts. Both authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The conclusions and opinions expressed in this paper are those of the authors and do not necessarily represent the views of the organizations with which the authors are affiliated or the funders.

Author contributions

Conceived and designed the study: AC, AMF. Performed the experiments/collected the data: AC. Analyzed and interpreted the data: AC, AMF. Contributed resources: AMF. Drafted or revised the manuscript: AC, AMF.

Competing interests

The authors have declared that no competing interests exist.

Data accessibility statement

All relevant data are within the paper.

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