

Exploring the knowledge, attitudes, and provision practices of pharmacists in Ontario:

A mixed-methods study dedicated to emergency contraception

By: Andréanne Chaumont

Supervisor: Angel M. Foster, DPhil, MD, AM

School of Interdisciplinary Health Sciences

Faculty of Health Sciences

University of Ottawa

June 2016

Submitted to the University of Ottawa in partial fulfillment of the requirements for the degree of

Master of Science in Interdisciplinary Health Sciences

© Andréanne Chaumont, Ottawa, Canada, 2016

Abstract

The availability of accessible, effective, and timely emergency contraception (EC) technologies is an important issue in women's reproductive health. In Canada, three methods of EC are currently available: the levonorgestrel pill (LNg-EC), the Copper-T intrauterine device (IUD), and ulipristal acetate (UPA). This study explores the EC knowledge, attitudes, and practices of Ontario pharmacists through a mixed-methods study. The mixed-methods study includes a bilingual mailed survey with a representative sample of retail pharmacists and in-depth interviews with a subset of respondents.

Results of the survey indicate that there is considerable interest among pharmacists to expand access to EC in Ontario; however, the results indicate that LNg-EC continues to be a behind-the-counter product and knowledge of other EC modalities is modest. Pharmacists view themselves as playing a critical role in patient education and counseling, as well as raising awareness about EC in the community. Developing and implementing continuing education efforts targeting pharmacists appears warranted. This research could ultimately play a role in expanding access to IUDs and UPA, as well as raising awareness of these modalities within the pharmacy community.

Résumé

La disponibilité à des technologies de contraception d'urgence (CU) accessible, efficace et dans un délai raisonnable est une problématique d'importance pour la santé reproductive des femmes. Au Canada, trois méthodes de CU sont actuellement disponibles : le comprimé de levonorgestrel (CU-LNg), le dispositif intra-utérin de cuivre (DIU) et l'acétate ulipristal (UPA). Cette étude multi-méthodes qui est composée d'une sondage bilingue posté à un échantillon représentatif de pharmaciens travaillant en milieu communautaire et d'entrevues réalisées avec un sous-ensemble de participants a pour but d'explorer les connaissances, les attitudes et la prestation de services des pharmaciens en Ontario par rapport à la contraception d'urgence.

Les résultats des sondages démontrent qu'il y a un intérêt considérable de la part des pharmaciens quant à l'amélioration de l'accessibilité à la CU en Ontario. Toutefois, nos résultats démontrent que la CU-LNg continue d'être un produit situé en Annexe II et que les connaissances des pharmaciens quant aux autres méthodes de contraception d'urgence sont limitées. Les pharmaciens croient qu'ils sont un élément clé pour l'éducation de leurs patients et pour prodiguer des conseils sur la CU dans la communauté. Le développement et l'implantation de formation continue spécifiques aux pharmacies sont nécessaires. Cette recherche pourrait favoriser l'accessibilité au DIU et à l'UPA en plus d'améliorer les connaissances de ces technologies au sein de la communauté pharmaceutique.

Acknowledgements

Dr. Angel Foster - without you this thesis project would not have been possible. Thank you for believing in my project. Further, a special acknowledgement to Dr. Foster's Endowed Chair in Women's Health Research funded by the Ontario Ministry of Health and Long-Term Care which covered the costs associated with the project.

Dr. Raywat Deonandan and *Dr. Karen Philips* - their feedback has been essential to completing such a rich project.

I will always be thankful to the *group of volunteers* and *Josée Riel* for their help during the data collection process. It made the process much smoother and I truly appreciated working with all of you.

I am grateful to *Dr. Sheila Dunn* and her team for both inspiring this study and for providing us with their original instrument.

Classmates - Thank you for the ongoing support though good and bad times.

SA - for the unconditional love and support.

Friends and Family - for their interest in my work.

And finally, MAL - Merci pour ta présence et simplement pour tout.

I would also like to acknowledge the generous contributions of the Ontario Graduate Scholarship Fund and the University of Ottawa which allowed me to dedicate time to collect data, write this thesis, and present the findings at conferences in Canada and in US.

Table of contents

Abstract	ii
Acknowledgments	iii
Table of contents	iv
List of appendices	vi
List of acronyms and abbreviations	vi
Chapter 1: Introduction	1
1.1 Background.....	1
1.1.1 The importance of emergency contraception	1
1.1.2 Overview of available emergency contraception methods.....	2
1.1.3 The Yuzpe method	3
1.1.4 The Copper-T IUD	3
1.1.5 Levonorgestrel EC pills.....	4
1.1.6 Low dose mifepristone	5
1.1.7 Ulipristal acetate.....	7
1.1.8 Role of pharmacists in EC service delivery in Ontario	8
1.2 Rationale.....	9
1.3 Specific objectives.....	9
1.4 Outline of thesis.....	10
Chapter 2: Methods	12
2.1 Component I – Mailed survey to pharmacists in Ontario.....	12
2.1.1 Piloting of the survey instrument	13
2.1.2 Data collection.....	13
2.1.3 Data entry	15
2.1.4 Data analysis	15
2.2 Component II – In-depth interviews with a sub-set of survey participants.....	16
2.2.1 Training and preparation for the interview.....	16
2.2.2 Data collection.....	17
2.2.3 Data analysis	18
2.3 Ethical considerations.....	19
2.4 Conceptual framework	19
Chapter 3: Article 1: The not so over-the-counter status of emergency contraception in Ontario: A mixed-methods study with pharmacists	20
Andréanne Chaumont, MSc(c), Angel M. Foster, DPhil, MD, AM	
Chapter 4: Article 2: “I wonder why Canada doesn’t have it yet?”: Exploring Ontario pharmacists’ knowledge of and interest in ulipristal acetate	37
Andréanne Chaumont, MSc(c), Angel M. Foster, DPhil, MD, AM	
Chapter 5: Discussion	56
5.1 Integration of results.....	56
5.1.1 Knowledge, awareness and education.....	57
5.1.2 Barriers in accessing EC	58
5.1.3 Attitudes and roles of pharmacists	61

5.1.4 Willingness of pharmacists to participate in and improve EC service delivery.....	62
5.1.5 UPA and the IUD as first options for heavier women	63
5.2 Suggestions for improving access to EC in the Ontario context	63
5.2.1 Education of the general population to promote use of EC	64
5.2.2 Other ways services could be improved.....	64
5.3 Significance and future directions	65
5.4 Limitations	66
5.5 Positionality as a researcher and reflexivity	67
5.6 Statement of contribution	68
5.7 Conclusion.....	69
Bibliography	71
Appendices	79

List of appendices

Appendix A: Health Canada warning included on Plan B® package

Appendix B: Research Ethics Board (REB) approval letter – Component I

Appendix C: Research Ethics Board (REB) approval letter – Component II

List of acronyms and abbreviations

BTC	Behind-the-counter
CE	Continuing education
CPhA	Canadian Pharmacists Association
EC	Emergency contraception
ECPs	Emergency contraceptive pills
IDIs	In-depth interviews
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
OCP	Ontario College of Pharmacists
OTC	Over-the-counter
PI	Principal investigator
REB	Research Ethics Board
UPA	Ulipristal acetate

Chapter 1: Introduction

1.1 Background

1.1.1 The importance of emergency contraception

The availability of accessible, effective, and timely emergency contraception (EC) modalities is an issue for women's reproductive health worldwide. Emergency contraception has offered women an effective way to prevent an unwanted pregnancy since the 1970s (Foster & Wynn, 2012). However, emergency contraception remains an underutilized contraception option for women of reproductive age.

In Canada, unintended pregnancies represent more than one third of all pregnancies (Fisher, Boroditsky, & Morris, 2004). A national survey published in 2004 indicated that 27% of respondents had experienced an unintended pregnancy (Fisher et al., 2004) and approximately one in three Canadian women will have an abortion over the course of their reproductive lives (Norman, 2012). On average, 100,000 abortions occur every year in Canada (Johnson, 2012), indicating that unintended pregnancy continues to be a major public health issue. Furthermore, the use of moderately effective contraceptive methods or the non-use of contraception is a major driver of unintended pregnancy; a national survey published in the *Journal of Obstetrics and Gynecology Canada* found that among sexually active women who did not desire pregnancy 50% were condom-only users and 15% used no method of contraception (Black et al., 2009). One study found that 36% of Canadian abortion patients were not using contraception during the month they became pregnant (Wiebe, 2013). The availability and accessibility of EC serves as an important intervention to unwanted pregnancy and precludes the need for an abortion.

Reproductive health services for Canadian women could be improved by increasing the number of available contraceptive methods and ensuring that they are accessible and affordable. Another factor of high importance to the improvement of reproductive health services is the

awareness and education of pharmacists of the available contraceptive methods (Foster & Wynn, 2012).

The need for improved access to reproductive health services and information is considerable and varies among different groups of women. Over the last five decades, there has been increased demand for access to a full range of safe and effective contraceptives. Indeed, the development of new contraception technologies continues to benefit from important investigation and research funding (Trussell, Raymond, & Cleland, 2015; Black & Guilbert, 2015).

Emergency contraception is underutilized when needed; however, research has demonstrated that increasing its timely access is positively correlated to the use of EC technologies (Raymond, Trussell, & Polis, 2007). The use of EC is restricted in a number of ways. For example, access to EC often depends on the geographic location and hours of service delivery points. Pharmacies play a critical role in ensuring access to EC services, as EC pills are mainly available in these health centers. Although EC is widely available in Ontario, the location of the pharmacy interferes with accessibility. Indeed, Dunn and colleagues (2008) demonstrated that the availability of EC varies between rural and urban areas due to pharmacy hours and physician availability. Rural pharmacies tend to be closed on weekends, especially Sundays, and have more limited opening hours.

1.1.2 Overview of available emergency contraception methods worldwide

Although methods to prevent pregnancy after unprotected intercourse have been used for almost half a century, the availability of EC varies widely throughout the world. The availability of medications, and therefore EC, is undeniably conditioned by political and regulatory complexities framed by each country's federal health system. Globally, there are five emergency contraception modalities: combined oral contraceptive pills (the Yuzpe method), the Copper-T

intrauterine device (IUD), progestin-only EC pills, low dose mifepristone, and ulipristal acetate (UPA). Below is a brief description of each modality listed chronologically.

1.1.3 The Yuzpe method

First developed in the 1970s, this combined hormonal method of emergency contraception has now largely been replaced by progestin-only EC. The Yuzpe method (named for the Canadian physician who initially proposed the regimen) is composed of existing oral contraceptive pills containing estrogen and progesterone. The respective dose of each hormone and the numbers of pills taken at the time of administration depends on the specific pill brand. For all brands, the Yuzpe method consists of a two dose regimen taken 12 hours apart. The primary mechanism of action is to inhibit or delay ovulation, therefore the regimen has greater efficacy if taken before ovulation (during the first half of the menstrual cycle). The Yuzpe method is effective up to 72 hours after sexual intercourse and is most effective when taken within 12-24 hours of sexual intercourse. In terms of efficacy, a meta-analysis concluded that the Yuzpe method prevented about 74% of expected pregnancies (Trussell, Rodríguez, & Ellerston, 1999). Side effects are similar to those reported with levonorgestrel emergency contraceptive pills (LNg-EC) although the frequency of nausea (50%) and vomiting (20%) is higher when using the Yuzpe method (Task Force, 1998). Despite no longer being in widespread use, the Yuzpe method remains an important option in settings where dedicated progestin-only products are unavailable or unaffordable.

1.1.4 The Copper-T IUD

The IUD is another option for post-coital pregnancy prevention. IUDs are a highly effective method of long-acting reversible contraception (LARC); they are 20 times more

effective in preventing pregnancy than oral hormonal modalities such as the progestin-only dedicated pill (Callegari et al., 2014). Evidence shows that IUDs containing copper “sleeves” with a surface area of at least 380mm² are the most effective for post-coital pregnancy prevention; they can be inserted up to 10 days following unprotected or under-protected intercourse (Cleland, Zhu, Goldstuck, Cheng, & Trussell, 2012). The main advantage of the IUD used as EC is that once inserted it continues to provide safe, highly effective, and reversible contraception for up to 12 years (Sivin, 2007). This method offers fewer opportunities for error because its efficacy does not rely on user compliance. The main side effects of the IUD are lower abdominal pain and bleeding associated with insertion.

Despite its efficacy, IUDs are rarely used in Canada for the purpose of emergency contraception. This is likely due to both the upfront costs associated with obtaining the device and the limited availability of trained health care professionals to provide immediate/timely insertion (Weir, 2003). The underuse of LARC methods is a common situation worldwide. A 2011-2013 survey among American women of reproductive age indicated that only 6.4% used an IUD as their contraceptive method (Daniels, Daugherty, & Jones, 2014). The use of the IUD is even lower in Canada (2.3%), especially in young (aged <20 years) and single women (Black et al., 2015; Hauck & Costescu, 2015).

1.1.5 Levonorgestrel EC pills

Levonorgestrel (LNg) is a synthetic molecule derived from 19-noresterone and is a member of the progestin family. A dose of 1.5mg of LNg reduces the risk of pregnancy by up to 89% when used within five days of unprotected or under-protected intercourse (Trussell, 2012; von Hertzen et al., 2002). LNg impacts the luteinizing hormone (LH) surge thereby delaying or inhibiting ovulation. Studies have shown that there is no effect on the endometrium and LNg-EC

will not interfere with an existing pregnancy (Trussell, Raymond, & Cleland, 2015). The main side effects reported by patients are headaches, menstrual changes, abdominal pain, fatigue, and nausea (Koyama, Hagopian, & Linden, 2013). Previous studies strongly suggest that LNg should be administered as soon as possible within 120 hours of unprotected or under-protected sexual intercourse.

Recent studies have questioned the efficacy of progestin-only EC when used by women over 75kg (HRA Pharma, 2014). Although the data is conflicting, Health Canada approved a label change warning that LNg-EC may be ineffective for heavier women in 2014 (Plan B, 2016). Canada is the only country in the world to have a weight restriction on the label (See Appendix A).

LNg-EC has been registered in over 150 countries and is available without a prescription in more than 60 countries (Foster & Wynn, 2012). Progestin-only EC has been available without prescription in Ontario since 2005. A study published in 2008 reported that 92% of Ontario pharmacies had Plan B® in stock after the regulatory change that made progestin-only EC available without a prescription (Dunn, Brown, & Alldred, 2008). LNg-EC obtained over-the-counter pharmaceutical status (Schedule III) under the National Drug Scheduling Advisory Committee (NDSAC) in 2008, meaning that a consultation with a pharmacist is no longer required to purchase the medication (Canwest News Service, 2008; National Association of Pharmacy Regulatory Authorities [NAPRA], 2008; NAPRA 2009).

1.1.6 Low dose mifepristone

Mifepristone is a synthetic steroid that also acts as an anti-progestin. It can be administered after a pregnancy is established (200mg to 600mg). This dosage has an abortifacient

effect and is highly effective at terminating an early pregnancy when used in combination with a prostaglandin. This same anti-progestin can be used as an emergency contraceptive when taken at lower doses (10mg or 25mg) within five days of unprotected or under-protected intercourse, especially if taken before ovulation. Mifepristone's mechanism of action as an emergency contraceptive is to reduce estrogen levels, thereby suppressing follicular development and delaying the maturation of the endometrium. The dosage consists of one 10mg or 25mg tablet and can be administered up to 120 hours after sexual intercourse.

Debate surrounding the efficacy of mifepristone as EC is still ongoing. A study carried out in China revealed that low doses of mifepristone (10mg to 25mg) were statistically more effective than LNG and had efficacy comparable to UPA (Cheng, Che, & Gülmezoglu, 2012). A more recent study concluded that this same dose of mifepristone does not represent a statically significant improvement in efficacy when compared to LNG (Koyama et al., 2013). The benefit of mifepristone is that unlike LNG-EC, its efficacy does not decrease over a five-day window. Mifepristone also has few reported side effects; the most notable side effect is a one-to-two week delay in menses, which is similar to UPA.

Mifepristone has been defined as the gold standard for early abortion and included in the World Health Organizations' List of Essential Medicines (Dunn & Cook, 2014). Despite having been accepted and distributed in more than 60 countries worldwide (including the United States) as a medication abortion method, relatively few countries (among them Armenia, China, Russia, and Vietnam) have registered mifepristone as an emergency contraceptive (Trussell, Raymond, & Cleland, 2015). This discordance is likely due to the political complexities surrounding a dual use medication that at low doses after sex prevents pregnancy but at higher doses after a pregnancy results in termination. As of July 2015, Health Canada registered mifepristone (and a prostaglandin) for early pregnancy termination under the brand name Mifegymiso® (Health

Canada, 2015). Low dose mifepristone for pregnancy prevention is not available in Canada and Mifegymiso® will not be able to be used off-label for this purpose.

1.1.7 Ulipristal acetate

Often referred to as a second generation EC technology, ulipristal acetate (UPA) is a selective progesterone-receptor modulator. The anti-progestin action of UPA can inhibit or delay ovulation by postponing the LH surge and likely alters the endometrial lining, thereby reducing the probability of implantation (Mansour, 2009). The dose consists of one 30mg tablet of UPA taken within five days of unprotected sex (Fine, 2011). The overall efficacy of UPA is greater than LNg-EC, especially 73-120 hours after sexual intercourse (Benagiano & von Hertzen, 2010). The most common side effects of UPA are abdominal pain and delayed menses (Mansour, 2009). There are also reports of headache, nausea, changes in mood, and vomiting. EllaOne® is covered under the Affordable Care Act in the United States but is only available by prescription, which may reduce timely access to the medication.

Ulipristal acetate was approved by Health Canada in 2014 for the treatment of uterine fibromas under the brand name Fibrystal® (Canadian Agency for Drugs and Technologies in Health, 2013). Fibrystal® is available as a 5mg pill but the product label makes no mention of using the medication as an emergency contraceptive. In September 2015, Health Canada approved UPA for use as an emergency contraceptive method under the brand name Ella® (Canadian Pharmacist's Letter, 2015). Ella® is distributed by Actavis Specialty Pharmaceuticals Co. in a 30mg tablet and is estimated to cost approximately CAD27 according to the Canadian Pharmacist's Letter (2015). It is only available by prescription after being treated by a physician. The introduction of Ella® into the Canadian health care system is an important step toward increasing access to effective post-coital contraceptive methods; however, given the window for

use, the prescription requirement will likely create barriers to timely access, particularly in rural areas.

1.1.8 Role of pharmacists in EC service delivery in Ontario

In Canada, progestin-only pills are the most widely used post-coital pregnancy prevention method. In the province of Ontario, progestin-only pills are available over-the-counter and directly from pharmacies (Dunn et al., 2008). Provincial community pharmacies carry three main brands: Plan B®, Next Choice® and Option 2®; the latter two are generics. Consequently, pharmacists play a critical role in EC service delivery. As patient-oriented health care professionals, pharmacists are available and accessible in their communities. They have the role to educate, counsel, and refer patients as needed and are key stakeholders in the introduction and promotion of medication. Further, pharmacists are committed to fulfilling the health care needs of their patients and are often open to change and to exploring a range of innovative service delivery strategies (Canadian Pharmacists Association [CPhA], 2016). Although the consultation of a pharmacist is not required in Ontario to obtain LNG-EC, pharmacists remain an important resource as they should be available to answer questions, provide evidence-based information to patients, and refer patients to other health care services when requested. In recent years there have been efforts to increase the timely availability of IUDs as EC and a pilot project in British Columbia has explored the development of “same day pharmacy referrals” for the immediate post-coital insertion of an IUD. To date there are no similar projects in Ontario.

Finally, the introduction of UPA into the Canadian health care system offers an opportunity for community pharmacists to play a critical role in EC service delivery. Physicians and pharmacists received a descriptive letter in November 2015 with details about the medication

(Canadian Pharmacist's Letter, 2015). Given its recent introduction it is likely that the medication is not yet available in Ontario pharmacies and that pharmacists throughout the province are not aware of UPA. Even though Ella® requires a prescription, pharmacists will likely participate in promotional efforts to enhance its use and will be called upon to answer questions about the medication.

1.2 Rationale

An exploration of Canadian pharmacists' knowledge, attitudes, and practices related to a range of emergency contraception modalities has not yet been published. By identifying the current gaps in EC service delivery in Ontario, pharmacists have the potential to advance efforts to increase access to a range of technologies as well as introduce more effective methods and innovative practices in the provincial health scheme. As frontline health care professionals, pharmacists play a critical role in the use and delivery of EC. A rigorous study has the potential to advance efforts to improve education and awareness amongst pharmacists, pharmacy educators, and professional societies of the province.

1.3 Specific objectives

A better understanding of Ontario pharmacists' knowledge about emergency contraception technologies, their attitudes toward them, and their current and potential provision practices will help address the gaps in our knowledge of current service delivery in the province. Obtaining pharmacists' opinions with respect to the introduction of EC technologies in Canada and the expansion of their role in EC service delivery will inspire recommendations to improve the current situation in Ontario.

Using a mixed method study design, this study aims to:

1. Evaluate Ontario pharmacists' knowledge of the five different emergency contraception technologies;
2. Explore Ontario pharmacists' attitudes toward emergency contraception technologies;
3. Examine current and potential EC provision practices; and
4. Explore Ontario pharmacists' responses to initiatives to enhance their role in IUD provision or the introduction of ulipristal acetate into the Canadian Health system.

1.4 Outline of thesis

I composed this thesis as a “Thesis by articles” consisting of a total of five chapters. In Chapter 1, I provide a literature review of the importance of emergency contraception in reducing unintended pregnancy rates and of the situation of emergency contraception in Canada and in Ontario. The first chapter also explains the importance of community pharmacists in EC service delivery and the reasons for focusing on the knowledge and practices of these health care professionals. Following this overview, I provide the rationale for undertaking this mixed-method study along with my research questions and objectives. I conclude this chapter by providing an outline of the thesis.

Chapter 2 describes the methods I employed to achieve the objectives of the study. I begin with a subsection dedicated to the mailed survey (Component I) where I describe the preparatory phase and development of the survey tools, data collection, and my analytic approach. Then I move to a description of the in-depth interviews with a sub-set of survey participants (Component II). I outline my training and preparation, data collection, and data analysis related to this component. At the end of this chapter, I explore the ethical considerations and provide the conceptual framework for my project.

In Chapter 3 and Chapter 4 I provide the bulk of my thesis composed of two research articles. In the first article (Chapter 3) I shed light on current practices with respect to the service

delivery of LNg-EC in Ontario and discuss gaps associated with the provision practices within pharmacies. We formatted the article for submission to *Contraception* and thus it conforms to the standards of that peer-reviewed journal.

In the second article (Chapter 4), I document the potential of introducing ulipristal acetate into the Canadian health care system and explore how pharmacists might respond to the introduction of a second generation EC pill. We formatted the article for submission to the *Journal of Obstetrics and Gynaecology Canada (JOGC)* and thus it conforms to the standards of that peer-reviewed journal.

The final chapter consists of a discussion section composed of various subsections. First, I begin Chapter 5 with a synthesis of the two articles and include a broader discussion of the main themes that emerged across both study components. In the discussion, I also integrate the main findings with respect to the Copper-T IUD and contextualize the results within the published literature on reproductive health in Ontario and in Canada. I follow this synthesis with a reflection on my positionality as a researcher and how my identities, values, and experiences influenced data collection, analysis, and interpretation. I then move to a discussion of the significance and implications of the research, including future directions for the project, before turning to the limitations and my positionality as a researcher. The final part of the chapter includes a statement of contribution and a conclusion. The overarching bibliography and appendices follow.

Chapter 2: Methods

Given the objectives of my thesis project we determined that a mixed-methods design was the most appropriate approach to explore our research questions. This mixed-methods study includes both a quantitative and a qualitative component and is informed by prior research on emergency contraception in Canada. First, this chapter provides a description of the quantitative component, which is composed of a survey from a sample of pharmacists in Ontario. Second, I provide a description of the qualitative component, which is composed of a sub-set of survey participants who participated in an in-depth interview. I conclude by exploring the ethical considerations and conceptual framework for this study.

2.1 Component I – Mailed survey to pharmacists in Ontario

In 2005, Dr. Sheila Dunn and her team at the University of Toronto conducted a survey immediately after LNg-EC became available without a prescription (Schedule II) in Ontario (Dunn et al., 2008). They aimed to determine whether the deregulation of LNg-EC in 2005 was associated with increased availability of the medication (Plan B®) in Ontario pharmacies, as well as examine barriers to access within pharmacies across the province. We received approval from the Principal investigator, Dr. Dunn, to model our survey off of their instrument. Rather than repeating the Dunn et al. (2008) study, we used their survey as inspiration for our project. We updated the instrument to reflect the 2008 regulatory change of LNg-EC, we included questions about all five modalities of EC, and we offered participants the option of completing the survey in either English or French.

2.1.1 Piloting of the survey instrument

In order to ensure that the survey was comprehensible to respondents, we piloted the instrument with both Anglophone and Francophone representatives from community retail pharmacies in the Greater Ottawa region. A total of nine Anglophone pharmacists and four Francophone pharmacists reviewed and completed the survey. We conducted the piloting process in person, which took place in early June 2015. We strategically visited pharmacies during times of the day when pharmacists were typically less occupied. After ensuring that the pharmacist could dedicate roughly 20 to 25 minutes to reviewing the instrument, we asked him/her to complete the survey in order to flag any questions that were potentially unclear or confusing. Once completed, we conducted a short debriefing interview with the pharmacist in order to understand points of confusion. We also timed the survey for length of completion. The piloting process allowed us to finalize the instrument after taking into account all comments and suggestions made by both Anglophone and Francophone pharmacy representatives.

We excluded the pilot pharmacies from the survey sample and we did not include completed pilot surveys in the final analysis. To thank them for their time, each participant received by email a \$25.00 gift certificate from Amazon.ca, although two of the 13 participants declined the compensation.

2.1.2 Data collection

From June 2015 to September 2015, we collected responses from survey participants from community-based retail pharmacies in Ontario. We created the study sample using a stratified random selection process using the Ontario College of Pharmacists (OCP) database. We accessed the database in May 2015 through the OCP website. We intentionally over-sampled independent pharmacies, pharmacies in rural areas, and pharmacies located in Franco-Ontarian communities.

Consistent with the Dunn et al. (2008) study design, we included only community-based retail pharmacies in the study and thus excluded pharmacies associated with hospitals or clinics and pharmacies based in army camp settings, for a total sample size of 1,428 pharmacies. We assigned each pharmacy a numeric digit in order to track non-respondents (0001 to 1428).

On four separate occasions over the data collection period, we invited pharmacists to participate in the survey. During the initial and third contact attempts, we mailed the full survey package, including the instruction letter, the bilingual survey instrument, a stamped return envelope, and a lottery and key informant interview response card. The introduction letter invited a representative from the pharmacy to complete a four-page survey dedicated to emergency contraception. We organized the questionnaire in four different sections. The first section was composed of demographic questions about the pharmacy, the catchment area, the population served, and the survey respondent. The second section included a series of closed-ended knowledge assessment and attitudinal questions related to all five modalities of emergency contraception, as well as a free response section for further comments. The third section explored current provision practices and interest in additional avenues for EC provision (including IUD referrals and provision of UPA once approved). In the final section, we offered participants an opportunity to comment on other issues related to EC and avenues to introduce new services related to EC. This final section also directed the respondent to a card on which he/she was to indicate interest in receiving the survey results and participating in a key informant interview. During the second and fourth contact attempts, we sent a reminder card to non-respondent pharmacies. We separated each contact attempt with non-respondent pharmacies by intervals of approximately four weeks.

During data collection, we used a substitution process in order to replace pharmacies that had defunct addresses. Using the numeric code attributed to the initial pharmacy, we identified a

substitute pharmacy in the same geographic region. However, once data collection was completed (after the final contact attempt), we continued to receive a fair number of envelopes from non-respondents or pharmacies with defunct addresses. Thus we removed a total of 32 pharmacies, which were closed or had moved locations, for an ultimate sample of 1396 community pharmacies. Over the data collection period, we collected a total of 198 completed mailed surveys from Ontario pharmacists, for a response rate of 14% (14.2%).

As an incentive, pharmacists who returned the completed questionnaire were eligible to receive a \$100.00 gift certificate from Amazon.ca. We offered one gift certificate for every 100 participants, thereby drawing two gift certificates for the respondents. We emailed the winners their gift certificates, as both pharmacists had provided the required information on their lottery cards. We collected the pharmacists' email addresses for lottery purposes only, and we did not use this information during our analysis.

2.1.3 Data entry

A group of volunteers entered the completed survey data into *Fluid Surveys*. We chose this online platform because it allows for creation of a user-friendly interface and easy export of survey data to IBM SPSS Statistics 23.0. We reviewed the data entered by volunteers in order to ensure accuracy of manual entry. We also audited 10% of the online entered survey data with the returned mailed surveys for each volunteer.

2.1.4 Data analysis

Using SPSS, we analyzed the responses with descriptive statistics, including frequencies and cross-tabulations. We used the pharmacy as the unit of analysis. Based on the Dunn et al. (2008) findings, we expected our data to have regional variance and thus we analyzed our data

for province-wide availability based on regional and rural/urban location of pharmacies. We conducted t-tests with continuous variables and chi-square and Fisher's exact for categorical and dichotomous variables. We set the two-tailed significance level at ≤ 0.05 . We exported open-ended questions to Microsoft Word® and analyzed the text of free response questions for content and themes.

2.2 Component II – In-depth interviews with a sub-set of survey participants

We invited all survey respondents to participate in an in-depth interview in order to understand better pharmacists' views on initiatives for expanding their role in IUD provision and eventual UPA service delivery.

2.2.1 Training and preparation for the interview

In 2014-2015, I served as the Francophone Study Coordinator for the Canada Abortion Study (CAS). My supervisor, Dr. Angel M. Foster, designed this national study in order to assess women's experiences obtaining abortion services across the provinces and territories and explore geographical disparities. As the Study Coordinator, I conducted more than 15 interviews with women to discuss their abortion experiences. I conducted interviews in both French and English and led recruitment efforts in Quebec.

Conducting these interviews prepared me for conducting interviews related to my own thesis project. After receiving constructive feedback from my thesis supervisor, as well as the overall CAS Study Coordinator, Kathryn LaRoche, I honed my active listening skills and my ability to communicate with empathy over the phone. Through this experience, I also obtained the opportunity to familiarize myself with the process of writing interview notes and memoing after each interview.

As my part of my training, I attended a session provided by Ms. LaRoche on how to transcribe interviews accurately and efficiently. I transcribed both French and English CAS interviews, a process through which I was able to practice my skills in both languages. By conducting interviews for CAS, I was able to practice capturing both verbiage and verbal utterances. Finally, I had the opportunity to present the preliminary findings from the Quebec study at the *7e Congrès International des Recherches Féministes dans la Francophonie* in August 2015. Preparing for this conference allowed me to gain experience in analyzing qualitative data and communicating research findings.

2.2.2 Data collection

As part of the mailed survey component, we invited survey respondents to participate in an in-depth follow-up interview. We sent an email invitation with an attached consent form to all survey participants who had indicated interest in the interview. For those who expressed interest, we scheduled the interview at a mutually convenient time.

Between July and October 2015, we conducted 15 English and two French in-depth interviews (IDIs) with 17 Ontario licensed pharmacists. We conducted the interviews over telephone or Skype using a semi-structured interview guide in either French or English, based on the pharmacist's preferred language. We sent each interviewee a \$20.00 gift certificate to Amazon.ca as a token of our gratitude for their participation.

In the interview, we asked the health care professionals a series of questions related to initiatives for expanding the service delivery practices of EC in both the province of Ontario and in Canada. The introductory section included questions related to the pharmacist's practice experiences and demographic information about the pharmacy. We then explored the participant's reaction to a hypothetical initiative promoting "same day pharmacy referral" for

post-coital IUD insertion. We then asked participants to comment on the possible introduction of UPA into the Canadian Health system. We ended the interview with a discussion about the ways in which EC service delivery could be improved in Ontario. With the permission of participants, we audio-recorded IDIs, which averaged 35 minutes in length.

The PI and the team of volunteers completed transcriptions of the interviews; the PI transcribed both French interviews and four volunteers transcribed the English interviews. The PI audited the transcripts of volunteers to ensure accuracy. Transcription took place from August to November 2015.

2.2.3 Data analysis

While conducting the interviews, I took written notes and wrote a memo shortly after the interview was completed. Writing memos served as an important tool in that it provided me with initial ideas about the organization of data analysis and helped me establish thematic saturation (Birks, Chapman, & Francis, 2008). I wrote the memos in the language of the interview in order to engage with the language of the participant.

We used ATLAS.ti to manage IDI data. Using our research questions and the interview guide, I developed a preliminary codebook composed of *a priori* codes and categories. As I explored the data, I added emergent codes and categories and recoded previously coded transcripts. Using an iterative process, I was able to identify major themes and relationships between the IDIs. Further reflection about the data and established networks between codes fostered my understating of the data and I was able to grant some meaning to the data thusly. Discussion with my supervisor guided the creation of the codes and the evolving codebook. We also reviewed the transcripts for horizontal and vertical coherence.

2.3 Ethical considerations

The two components of this project received approval from separate Research Ethics Boards (REBs) at the University of Ottawa. We received approval for the survey component of the project from the Health Sciences and Sciences REB (File #H03-14-20). We received approval for the in-depth interview component of the project from the Social Sciences REB (File #02-15-12). We have provided copies of both certificates of approval as Appendix B and Appendix C.

2.4 Conceptual framework

The goal of this thesis is to have a better understanding of the service delivery of emergency contraceptives within community pharmacies in Ontario. This research is intended to be exploratory in nature, with the aim of determining priorities for improvement and avenues for action. Consequently, this project is guided by the Promoting Action on Research Implementation in Health Services (PARiHS) framework, a framework that supports an exploratory phase to build a body of evidence to then influence practices and systems changes (Harvey & Kiston, 2016). This theoretical framework promotes successful translation of knowledge into practice in a given health context and informs our overall dissemination strategy.

Chapter 3: Article 1

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

We submitted this article to *Contraception* in May 2016. The article has been formatted per the guidelines of this specific peer reviewed journal.

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

Andréanne Chaumont¹
Angel M. Foster, DPhil, MD, AM^{1,2*}

- 1) Faculty of Health Sciences, University of Ottawa, Ottawa, ON, Canada
2) Institute of Population Health, University of Ottawa, Ottawa, ON, Canada
* Corresponding author

Acknowledgements: Andréanne Chaumont received the Queen Elizabeth II Graduate Scholarship in Science and Technology and several grants from the University of Ottawa to support this project. Dr. Foster's Endowed Chair in Women's Health Research is 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 would like to thank Drs. Raywat Deonandan and Karen Phillips for their feedback during various phases of this project and Dr. Shelia Dunn for providing us with her survey instrument. We are also grateful to the team of volunteers for their efforts. The conclusions and opinions expressed in this article are those of the authors and do not necessarily represent the views of the organizations with which the authors are affiliated or the funders.

Conflicts of interest: The authors declare that they have no conflicts of interest, financial or otherwise.

Word counts: Abstract: (250)

Manuscript (excluding title page, abstract, references, tables): 3,017

Introduction (385), methods (713), results (1,345), discussion/conclusion (574)

Keywords: Emergency contraception, levonorgestrel, Canada, reproductive health

Running title: Emergency contraception availability in Ontario

Submitted to: *Contraception*

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

Abstract

Introduction: In Canada, the progestin-only dedicated pill, widely known by the brand name Plan B®, is the most widely used method of emergency contraception (EC). This method obtained over-the-counter status in Ontario in 2008. Our mixed-methods study explored the knowledge, attitudes, and provision practices of Ontario pharmacists with respect to this modality of EC.

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 purposively oversampled pharmacies located in rural areas to explore a range of barriers to access. We analyzed the data using descriptive statistics and for content and themes using deductive and inductive analytic techniques.

Results: Results from the bi-lingual (English-French) survey indicate that Ontarian pharmacists' knowledge of progestin-only EC is generally accurate, but confusion persists about the mechanism of action and the number of times the drug can be used in on menstrual cycle. Despite the current regulatory status, 49% of our survey respondents indicated progestin-only EC pills are only available behind-the-counter, thus requiring women to engage/consult with a pharmacist. Our respondents strongly support 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 to engage with health service providers, including pharmacists, about all modalities of EC available in Canada.

Implications: Nearly a decade after the regulatory status change, almost half of Ontario pharmacies still carry progestin-only EC pills behind-the-counter. With the introduction of UPA, reproductive health advocates and educators have an opportunity to support efforts to improve information about, service delivery of, and access to a range of EC modalities.

1. 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 are all available methods of emergency contraception (EC). Ulipristal acetate (UPA) was approved for use as a post-coital contraceptive in 2015. However, the most widely used method of EC by Canadian women is the progestin-only emergency contraceptive pill [1].

In Ontario, Canada's largest and most populous province, progestin 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 [2]. 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 deregulated progestin-only EC to a Schedule III drug, moving it from behind-the-counter (BTC) product to over-the-counter (OTC) [3,4,5,6]. 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 generics brands (Next Choice® and Option 2®). In response to recent studies that suggest that progestin-only EC may be less or not at all effective when used by heavier women [7,8,9], in 2014 Health Canada issued a warning stating that progestin-only EC may be less effective in women weighing over 165 pounds and ineffective in women weighing over 176 pounds [10].

As patient-oriented health care professionals, pharmacists are available and accessible to their communities and thus play a critical role in EC service delivery. However, the scientific

literature on Canadian pharmacists' EC knowledge and attitudes is scarce. 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 LNG-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 article we focus on the findings that are specifically related to progestin-only EC pills.

2. Methods

2.1 Study design and data collection

Our study comprised two components; a mailed survey to Ontario pharmacists and in-depth interviews with a sub-set of survey respondents. With permission, we based our selection of pharmacies and the design of our survey instrument on a study conducted by Dunn and colleagues in the wake of the switch to BTC status [2].

We used a database from the Ontario College of Pharmacists to obtain our sample of community-based retail pharmacies, of which there were 4,232 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 1,428 pharmacies in June 2015; after accounting for closed pharmacies and inaccurate addresses we ultimately surveyed 1,396 pharmacies.

We contacted pharmacies four times over the course of the study period. The first contact included a bi-lingual (English-French) survey package comprised of 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 CAD100 gift card (one per 100 respondents). We sent

non-respondents a reminder postcard after one month. Continued non-respondents received a second survey package and a final reminder postcard three months and four months after the initial mailing, respectively. We included in our analysis all surveys received before the end of calendar year 2015.

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 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 minutes.

We invited respondents to participate in a telephone/Skype follow-up interview to discuss issues related to service delivery in depth. AC, a Master's student in Health Sciences at the University of Ottawa conducted all English and French interviews, after receiving training from her supervisor (AF), a qualitative researcher with experience leading 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 minutes, and offered all participants a CAD20 gift certificate. AC took notes during and wrote formal memos immediately after each interaction.

2.2 Data analysis

We entered 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 and Chi-Square analysis and Fisher's exact test to detect regional differences and difference 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 that started during data collection. AC or a study volunteer transcribed interviews verbatim and we used ATLAS.ti 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 AF 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.

2.3 Ethical considerations

We received ethics approval from the Research Ethics Boards at the University of Ottawa (File# H03-14-20 and 02-15-12). Throughout this manuscript we have redacted or masked all personally identifying information about individual pharmacists and their pharmacies.

3. Results

3.1 Description of participants and their pharmacies

We received 198 surveys (response rate of 14.2%) and all but two surveys were completed 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 minutes' drive from another pharmacy. We provide detailed information about the characteristics of these pharmacies in Table 1.

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

3.2 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 the evidence-based regimen of 1.5mg of levonogestrel 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 pharmacists reported that progestin-only EC must be taken within 72 hours (n=145, 75.1%) or within 120 hours (n=29, 15.0%) and 72.8% (n=142) correctly indicated that efficacy decreases when the drug taken more than 24 hours after intercourse.

However, our survey results indicate that confusion persists surrounding the 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 which 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 the Health Canada's warning, 70.5% (n=134) of our participants reported that the efficacy of progestin-only EC is lower in women weighing 75kg or more. Several of our in-depth interview participants also discussed the weigh-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 deliver it or not. If an 80kg women does not want to become pregnant I do not want to be the cause. There are few side effects, no down sides [to LNG-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.

3.3 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 product, the reported price ranged from CAD20 to CAD60 (approximately USD15 to USD45); 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 one to more than 50 each month; the majority of respondents (n=145, 83.8%) reported receiving 1-5 requests per month.

Despite the longstanding 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 four 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 the product BTC in order to counsel patients or provide 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 [that's] 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 and the absence of space factored into placement decision-making regarding placement. Two of our interviewees kept the medication BTC because of a lack of understanding of the current regulations.

3.4 Progestin-only provision practices

In general, survey respondents reported that pharmacies provide a dedicated space (n=178, 93.7%) for consultation and about a third (n=70, 36.8%) sometimes use a screening or

counselling tool during an EC-related consultation. Interview participants reported providing those seeking progestin-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 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 not having the medication in stock (n=16, 37.2%) or because the unprotected intercourse occurred outside of the timeframe for use (n=14, 32.6%), of confirmed or suspected pregnancy (respectively n=13, 12.6%), the patient did not present in person (n=10, 23.3%), or the patient had 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 though 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].

4. Discussion

4.1 General implications

Our results suggest that in-stock availability of progestin-only EC remains comparable to the findings of Dunn and colleagues in 2008 [2]. However, despite the regulatory change that subsequently took place, nearly half of our survey participants reportedly carry at least one progestin-only product BTC. A number of studies in North America have indicated that BTC status poses a barrier to timely access [11,12,13]. Thus, circulating a reminder about progestin-only EC's OTC status through a trusted source, such as the Canadian Pharmacist's Letter, appears warranted.

However, Canadian pharmacists have been longstanding advocates of BTC status [14,15]. Indeed, our interviews highlighted that for many pharmacists the decision to carry EC BTC is not based in misinformation about the regulatory status but in a belief that a consultation is necessary and valuable. Yet our results our results suggest that pharmacists still demonstrate knowledge deficiencies with respect to 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 [16,17] and may increase the 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 spring of 2016, Canada is the only country that has a formal warning about the association between weight and efficacy on the label of progestin-only products. This has undoubtedly caused confusion among health care providers and anecdotal evidence suggests that practices in Canada are inconsistent [10]. Our findings further confirm that pharmacists have operationalized this label change in different ways. Black & Gilbert recently issued recommendations to address this issue [18] and our results suggest that dissemination of evidence-based guidelines about the relationship between efficacy and weight and a reminder to pharmacists that as an OTC produce all people should be able to purchase the medication is a priority.

Finally, the recent introduction of UPA into the Canadian Health system offers an opportunity to engage in discussion with both health services professionals and the public about all EC modalities. This is especially important given the different regulatory statuses that UPA (prescription required) and progestin-only EC (OTC) will 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.

4.2 Limitations

Despite four contacts, the response rate to our survey was low, at less than 15% and represents less than 5% of retail pharmacies in Ontario. It is possible that we could have received a higher response rate had we conducted an online survey. Further, 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.

4.3 Conclusion

Health Canada's recent approval of ulipristal acetate for use as a post-coital contraceptive may provide a window of opportunity to engage 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.

References

1. Soon JA, Levine M, Osmond BL, Ensom MHH, Fielding DW. Effects of making emergency contraception available without a physician's prescription: A population-based study. *CMAJ* 2005;172:878-883.
2. Dunn S, Brown ERT, Alldred J. Availability of emergency contraception after its deregulation from prescription-only status: a survey of Ontario pharmacies. *CMAJ* 2008;178(4):423-424.
3. Eggertson L. Plan B comes out from behind the counter. *CMAJ* 2008;178(13).
4. Canadian Women's Health Network. Improving Access to Emergency Contraception. Women and Health Protection and Canadian Women's Health Network 2005 [Cited 15 May 2016]. Available from: <http://www.cwhn.ca/en/node/26942>
5. Canwest News Service. Morning-after pill approved for over-the-counter sales, 2008 May [Cited 16 May 2016]. Available from: <http://www.canada.com/topics/news/story.html?id=eb9a322c-0b86-414c-8a28-a21d22c8c6a3>
6. National Association of Pharmacy Regulatory Authorities. Drug Information Resources – Emergency contraception. 2009. [Cited 24 March 2016]. Available from: http://napra.ca/pages/Practice_Resources/drug_information_resources.aspx?id=2141
7. Kapp N, Abibol JL, Mathé H, Scherrer B, Guillard H, Gainer E, et al. Effect of body weight and BMI on the efficacy of levonorgestrel emergency contraception. *Contraception* 2014;91:91-104.
8. Gemzell-Danielsson K, Kardos L & von Hertzen H. Impact of bodyweight/body mass index on the effectiveness of emergency contraception with levonorgestrel: A pooled-analysis of three randomized controlled trials. *Curr Med Res Opin* 2015;31(12):2241-48.
9. Glasier A, Cameron ST, Blithe D, Scherrer B, Mathe H, Levy D, Gainer et al. Can we identify women at risk of pregnancy despite using contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception* 2011; 84: 363-67.
10. Eggerston L. Plan B emergency contraception may be ineffective for heavier women. *CMAJ* 2014;186(1):E21-22.
11. Canada Gazette. Regulatory impact analysis statement, Part II. 2005;139,857-71.
12. National Advisory Committee on Emergency Contraception (NACEC). National Advisory Committee on Emergency Contraception: Background. 2003. [Cited 20 April 2016]. Available from : http://www.pharmacists.ca/content/about_cpha/whats_happening/cpha_in_action.
13. Cohen MM, Dunn S, Cockerill R, Brown TE. Emergency contraception: models to increase accessibility. *J Obstet Gynaecol Can* 2015;25(6):499-504.
14. Canadian Pharmacists Association (CPhA). Motion on emergency contraception. 1999. [Cited 14 May 2016]. Available from: http://www.pharmacists.ca/content/hcp/Resource_Centre/
15. Erdman JN. Canada: Competing Frames of Access and Authority. *Emergency contraception: The story of a global reproductive health technology*. In: Foster AM, Wynn LL, editors. New York, NY: Palgrave Macmillan;2012,p. 57-78.
16. Trussell J. Emergency contraception: Hopes and realities. *Emergency contraception: The story of a global reproductive health technology*. In: Foster AM, Wynn LL, editors. New York, NY: Palgrave Macmillan; 2012, p. 20-35.

17. Raymond EG, Creinin MD, Barnhart KT, Lovvorn AE, Rountree W, Trussell J. Meclizine for prevention of nausea associated with emergency contraceptive pills: a randomized trial. *Obstet Gynecol* 2000;95:271-7.
18. Black A, Guilbert E. Canadian Contraception Consensus (Part 1 of 4). *J Obstet Gynaecol Can* 2015; 37(10):936-38.

Table 1: Survey respondent pharmacy demographics (N=198)

	n (%)
Type of pharmacy	
Independent	77 (39.1)
Chain	60 (30.5)
Banner	51 (25.9)
Other/no response	10 (5.07)
Region 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 of pharmacy	
Urban	128 (65.0)
Rural	69 (35.0)
No response	1 (0.5)
Another pharmacy located within a 15 minutes' drive	
Yes	180 (90.9)
No	18 (8.6)
No response	1 (0.5)
Store hours*	
Weekdays	198 (100)
Saturdays	189 (95.5)
Sundays	163 (82.3)
Principal languages spoken by pharmacy staff*	
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*	
English	191 (97.0)
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)

* Does not total 100% as respondents could select multiple responses

Chapter 4: Article 2
“I wonder why Canada doesn’t have it yet?”:
Exploring Ontario pharmacists’ knowledge of and interest in ulipristal acetate

We have prepared this manuscript for submission to JOGC and have formatted the article accordingly. However, because we want to build on the information presented in Chapter 3, we will submit this manuscript in the summer of 2016 once the other manuscript has been accepted for publication.

**“I wonder why Canada doesn’t have it yet?”:
Exploring Ontario pharmacists’ knowledge of and interest in ulipristal acetate**

Andréanne Chaumont, MSc (c)¹
Angel M. Foster, DPhil, MD, AM^{1,2*}

- 1) Faculty of Health Sciences, University of Ottawa, Ottawa, ON, Canada
 - 2) Institute of Population Health, University of Ottawa, Ottawa, ON, Canada
- * Corresponding author

Conflicts of interest: The authors declare that they have no conflicts of interest, financial or otherwise.

Word counts: Abstract: (272)

Manuscript (excluding title page, abstract, acknowledgements, references): 3,422

Running title: Ontarian pharmacists’ knowledge of and interest in UPA

Formatted for: Journal of Obstetrics and Gynaecology Canada

Full contact information for the corresponding author:

Angel M. Foster, DPhil, MD, AM
Institute of Population Health
1 Stewart street, 312-B
Ottawa, ON K1N 6N5
Canada
Phone: 613-562-5800 ext. 2316
Email: angel.foster@uottawa.ca

**“I wonder why Canada doesn’t have it yet?”:
Exploring Ontario pharmacists’ knowledge of and interest in ulipristal acetate**

Abstract

Objectives

In 2015, Health Canada approved the registration of ulipristal acetate (UPA) as a post-coital contraceptive. Our study aimed to explore Ontario pharmacists’ knowledge of and interest in the introduction of UPA into the Canadian Health system, before its registration as an emergency contraceptive (EC) method.

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 representatives. We analyzed the data for descriptive statistics and for content and themes that are associated to the introduction of ulipristal acetate into the Canadian Health system using both deductive and inductive techniques.

Results

Results from this study demonstrate that pharmacists were unknowledgeable of UPA. Our respondents strongly support the introduction of UPA and expressed positive thoughts about its potential to address some of the current gaps in EC service delivery in Ontario. The majority of our respondents indicated they would provide UPA once approved. Our participants identified a number of barriers to its introduction that include lack of education and awareness among the general community about EC, especially other than LNG-EC, and the cost of EC.

Conclusion

Ontario pharmacists strongly support the introduction of UPA into the Canadian Health system. As frontline healthcare professionals they believe they will play a significant role in educating future patients on the technology as well as raising awareness throughout the community. Further, promotion of Ella® by engaging with pharmacists and supporting continuing education efforts appear warranted.

Keywords: Canada, emergency contraception, pharmacy, reproductive health, UPA

Introduction

Unintended pregnancies remain a significant public health issue worldwide. In Canada, 27% of pregnancies are unplanned¹ and approximately one in three Canadian women will have an abortion over the course of their reproductive lives.² The majority of Canadian women who experience an unwanted pregnancy were either using a lower tier contraceptive method or no contraception in the month they became pregnant.³ Thus expanding contraceptive options for women, including a full range of effective methods, is a priority.

Emergency contraceptives are medications and devices that are used after sex to reduce the risk of pregnancy. Some modalities of emergency contraception (EC), including the post-coital use of combined hormonal pills (the Yuzpe method) and the post-coital insertion of the Copper-T intrauterine device (IUD) have been available in Canada for decades.⁴ However, the most widely used method in Canada is the levonorgestrel emergency contraceptive pill (LNg-ECP). In Ontario, LNg-ECPs have been available over-the-counter (OTC) since 2008.⁵ A 2008 study by Dunn and colleagues found that 93% of community pharmacies in Ontario had LNg-EC⁶ and a recent study by Chaumont and Foster confirmed that the overwhelming majority of pharmacies in Ontario have LNg-EC in-stock.⁷

In 2015, Health Canada approved the use of ulipristal acetate (UPA) for EC. Often referred to as a second-generation of EC technology, UPA is a selective progesterone-receptor modulator.⁸ When taken within 120 hours after unprotected or under-protected intercourse 30mg of UPA reduces the risk of pregnancy, primarily by delaying or inhibiting ovulation.⁸⁻⁹ Compared to LNg-EC, the overall efficacy of UPA is greater, especially during the 73-120 hour window.¹⁰⁻¹² Like LNg-EC, the side effects of UPA are tolerable and transient.¹³

Although a low-dose version of UPA had been available in Canada for the treatment of uterine fibroids, the recent Health Canada decision allowed Canada to join the more than seventy

countries that have already introduced this modality of contraception.¹⁴ Ulipristal acetate has been available in Europe since 2009 and in 2014 the European Medicines Agency (EMA) recommended provision without a prescription.¹⁵ In 2010, the US Food and Drug Administration (FDA) approved the drug for prescription use.¹⁶ Consistent with the status of all newly registered drugs, UPA (sold under the brand name Ella®) requires a prescription in Canada and retails at around CAD27.¹⁷

Incorporation of UPA into the Canadian health system is especially important because of Health Canada's warnings about the reduced efficacy of LNG-EC when taken by heavier women. In recent years, several studies have called into question the efficacy of LNG-EC when taken by women weighing 75kg or more¹⁸⁻²⁰ but after considerable evaluation both the EMA and the US FDA determined that the evidence was insufficient to warrant a change to LNG-EC product labels.²¹⁻²² Health Canada pursued a different course and in 2014 requested changes in the label warning that LNG-EC may have reduced efficacy if taken by women weighing 75-80kg and may have no efficacy if taken by women weighing more than 80kg.²³ As of early 2016, Canada is the only country in the world that requires inclusion of this warning on the LNG-EC label. Thus the introduction of UPA has the potential to be an especially important option for heavier women in Canada who may be denied LNG-EC.²⁴

In the summer and fall of 2015, we conducted a mixed-methods study in Ontario. The aim of the overall project was to explore the knowledge, attitudes, and practices of Ontario pharmacists with respect to a range of EC modalities and to identify possible ways in which pharmacists could become integrated into the provision of more effective EC technologies. In this article, we focus specifically on the findings related to ulipristal acetate.

Methods

Study design and data collection

Our study was comprised of two components: a survey of Ontarian pharmacists and follow-up interviews with a sub-set of survey respondents. In phase one, we mailed a bi-lingual (English-French) survey to a representative sample of retail pharmacies in the province. We used a stratified random selection process to draw our sample from the Ontario College of Pharmacists database and intentionally over-sampled independent pharmacies, pharmacies in rural areas, and/or pharmacies located in Franco-Ontarian areas. We excluded army base, clinic, and hospital pharmacies which resulted in an overall pool of 4,232 pharmacies. After accounting for defunct addresses we ultimately included 1,396 for inclusion in the study.

We contacted pharmacies four times over the course of the study. Our initial survey package included an instruction letter (addressed to the head pharmacist), the survey instrument, a stamped return envelope, and an invitation card to participate in a lottery (for a CAD100 gift card) and/or an in-depth interview (IDI). We sent reminder postcards to non-respondents after 4-6 weeks, a second full survey packet to continued non-respondents after another 4-6 weeks, and a final reminder to ongoing non-respondents after another 4-6 weeks. We launched the survey in June 2015 and included in our analysis all surveys received before the end of that calendar year.

We have described our survey instrument in detail previously.⁷ In brief, our questionnaire included four primary domains centered on participant and pharmacy demographics, knowledge and opinion about all modalities of EC, including a series of questions about UPA, current LNG-EC provision practices, and avenues for improving knowledge of and service delivery around EC. We also invited respondents to comment on any EC-related issue in a free response space.

In the second component of the project, we conducted IDIs with Anglophone and Francophone pharmacists throughout the province. We scheduled telephone/Skype interviews

with survey respondents who indicated interest between July 2015 and October 2015 (inclusive). After receiving training from her supervisor (AF), AC, a master's student at the University of Ottawa conducted all interviews. With permission, we audio-recorded all interviews which averaged 35 minutes in length. AC took notes during the interview and formally memoed immediately after each encounter. The process of memoing served to initiate the analytic process and establish thematic saturation.

Using an interview guide developed specifically for this study, and after obtaining verbal consent, we began the interview with questions about the participants educational and professional background as well as his/her current EC provision practices. We then turned to a discussion of the IUD as EC and possible avenues for increasing access to this form of post-coital contraception. We then turned to a discussion of UPA. We began by exploring the participants' knowledge of UPA and its availability and status in Europe, the US, and Canada. For those participants who were unfamiliar with UPA we provided a brief, standardized description of the medication, including indications, dose, route of administration, mechanism of action, side-effects, and efficacy. We then asked participants their opinion about UPA and the possibility of introducing UPA into the Canadian health system. We concluded this section of the interview with a discussion of ways in which pharmacists could be involved in the provision of UPA once introduced for post-coital use. In the final section of the interview we asked participants to further reflect on ways in which service delivery of EC, in general, could be improved. All participants received a CAD20 gift certificate to www.amazon.ca.

Data analysis

We entered survey responses into FluidSurveys and exported our data to IBM SPSS 23.0 for statistical analysis. We analyzed survey questions using descriptive statistics and free response questions for content and themes. We transcribed interviews verbatim and analyzed them for content and themes using both deductive and inductive techniques. We managed our qualitative data, including transcripts, notes, and memos, with ATLAS.ti. We analyzed each component of the project and then in the final phase of the analysis we integrated the findings, paying special attention to issues of concordance and discordance. Our interpretation of the findings derived from regular team meetings and discussions.

Ethical considerations

We received approval for this study from the Health Sciences and Sciences Research Ethics Board (REB) (File# H03-14-20) and the Social Sciences and Humanities REB (File# 02-15-12) at the University of Ottawa. In this paper we focus on the findings related specifically to UPA and have redacted or masked all personally-identifying information about participants, their patients, and their pharmacies.

Results

Participant characteristics

We received 198 complete/partially complete surveys for a response rate of 14.2%. Our survey respondents worked throughout the province, with the largest number in the south (n=91, 46.7%) and central (n=41, 21.0%) regions. More than two-thirds of our respondents worked in either independent pharmacies (n=77, 39.1%) or chain stores (n=60, 30.5%). We received only two surveys in French. We conducted 17 in-depth interviews with pharmacists practicing in Ontario. Our participants had been practicing for one to 40 years and worked in the central (n=4), east (n=3), north (n=5), and south (n=5) regions of the province. The majority of our participants (n=12) were women, more than half worked in either an independent or a chain pharmacy, and 11 participants worked in urban pharmacies. We conducted two interviews in French.

Knowledge of ulipristal acetate was minimal

Both components of the study suggest that baseline knowledge of UPA is minimal. Our survey respondents evidenced little detailed knowledge of the medication; about a third (n=71, 35.9%) knew that UPA could be used up to 120 hours after sex and most pharmacists reported that they did not know UPA's efficacy (n=163, 82.3%) or side effects (n=142, 71.8%). In our interviews, almost all participants did not know very much about UPA, although one participant explained that after taking the survey she looked up information about the medication to familiarize herself with the drug and two had some familiarity with the use of UPA (Fibristal®) to treat uterine fibroids. As one pharmacist practicing at a banner pharmacy in the northern Ontario explained, "Never came across it really, never had a prescription or anything. I mean, the name rings a bell, but that's all."

Pharmacists expressed enthusiasm about the introduction of UPA

“That is wonderful! There is an alternative which is going to be available. The more options the better...” (Pharmacist working in an independent pharmacy in southern region of Ontario)

After providing interviewees with a brief standardized description of UPA, all but two of our participants expressed strong support for the introduction of UPA into the Canadian health system. The availability of UPA in both Europe and the US reassured our participants about the safety of the medication. However, this also raised questions among our participants as to why UPA was not yet available. A pharmacist who works in a chain pharmacy in the central region asked, “I mean it sounds interesting... I wonder why Canada doesn’t have it yet? It is the company that just never particularly applied for like...is it a political thing?” Our interviewees were particularly interested in being able to offer a new product that works better over a longer period and is likely more effective when taken by heavier women. As one participant practicing in a retail pharmacy in eastern Ontario explained, “I think the introduction of UPA is interesting given the [few options] we have. We can offer [to heavier women] Plan B® and the insertion of [the] IUD, but we cannot do anything else...these women need another method of contraception that is efficient and reliable.”

Two pharmacists expressed uncertainty as to whether or not UPA should be introduced in Canada. Both explained that their lack of familiarity with the second generation EC pill made them unsure. In addition, both of these pharmacists expressed concern that patients would have “too many choices,” a situation that could lead to confusion. A pharmacist from a retail pharmacy in southern Ontario stated, “I am worried about patients coming and needing help and having too many choices. If it would be only one option, like the one you are talking about now, it is not too much more expensive, but more effective, then it would maybe be the main option compared to Plan B. Makes me think that they wouldn’t market Plan B® anymore.”

If registered, pharmacists would carry the product

Unlike our interviewees, our survey participants did not benefit from a description of UPA. However, more than half (n=116, 58.6%) indicated that would offer UPA once approved and available. A third of our survey respondents (n=66) reported uncertainty and attributed this to a lack of knowledge about the medication. However, analysis of the free responses of these participants suggests that most would provide UPA if reassured of its safety and efficacy.

Almost all of our interviewees reported that they would offer UPA if and when the product was approved and available. However, interviewees had widely varied opinions as to what regulatory status the drug should have. Five of our interviewees explained that UPA should follow a similar path to LNg-EC and eventually become a Schedule III drug, once awareness was raised in both the medical community and among the general population. A pharmacist from the central region working in a banner pharmacy summed this up, “[It’s] just because we aren’t familiar with it, you know as time goes by it can probably just go over-the-counter.”

The other twelve pharmacists felt that UPA should become a Schedule II drug. There was consensus among these interviewees that physician involvement was not required. However, most of our participants believe that requiring a consultation with a pharmacist is important. Pharmacists explained that their involvement was needed to ensure patient safety, provide patients with information about side effects and drug interactions, and minimize repeat use. As a pharmacist who works in a chain pharmacy in eastern Ontario explained, “I think the pharmacist should have some say in how it rolls out, even though it’s been on the market [in other countries] forever but you know.”

Pharmacists identified a number of challenges that will need to be overcome

“I don’t think there’s enough information given to the general public about what other [EC] options are. This is unfortunate “(Pharmacist working a chain pharmacy in the south)

Despite participant enthusiasm about the potential introduction of a new modality of EC, pharmacists identified a number of challenges to uptake. First and foremost, pharmacists focused on the overarching lack of knowledge about UPA within both the medical community and among potential users. Our participants expressed considerable interest in participating in continuing education programs to improve their own knowledge of EC technologies and emphasized that once armed with information they would be well positioned to raise awareness within their communities. As explained by a pharmacist from a banner pharmacy in northern Ontario:

I would also suggest promoting EC education...They should talk about it as part of health courses since a large number of adolescents have no idea of what we are talking about during our counselling sessions. I mean we could always go and give talks ourselves, especially in smaller communities.

Pharmacists also expressed concerns about the price and coverage of the medication. Several pharmacists drew from their experiences with LNG-EC and noted that a new product would likely be expensive and thus inaccessible to low income and young women. Ten of our interviewees indicated that the introduction of UPA should be accompanied by efforts to extend coverage of all EC products. As a pharmacist from the south region working in a chain pharmacy offered, “I think everyone who needs it should have access to it, regardless of costs and nobody should pay [have to pay out-of-pocket] for it. Costs shouldn’t get in the way of someone who needs [EC].”

Finally, several pharmacists noted that in Canada emergency contraception has become synonymous with Plan B®. Thus a challenge with the introduction of UPA would be working

with patients to understand that there are different modalities of EC with different advantages and disadvantages. Our participants suggested that uptake might be muted in the beginning as patients could be resistant to change. As described by a pharmacist in the central region working in a banner pharmacy:

For patients, I don't know if there is a way to educate them too, since you can't advertise directly to the patient...I'm thinking that patients will come in if they need emergency contraception and just ask for Plan B®. And they won't know that there might be other options. So [that is the] point when you could educate the patients, tell them what the other options are.

Discussion

Ella® officially entered the Canadian market in September 2015 as a Schedule I drug.²⁵ Although no sales data were available as of May 2016, given the experiences in other countries it is likely that adoption of UPA will initially be slow.²⁶⁻²⁷ However, incorporation of UPA into the Canadian health system marks an important step in expanding access to a full range of emergency contraceptive technologies.

Our findings indicate that baseline knowledge of UPA is minimal among pharmacists in Ontario. This is hardly surprising given that we conducted our survey before the introduction of UPA. But importantly, once provided with information about UPA, there appears to be significant interest among pharmacists as well as a stated intention to carry the product. Pharmacists are poised to be champions of UPA and will have significant responsibility for providing information about this new modality of EC to patients. Thus proactively engaging with pharmacists and raising awareness about UPA within this group of health professionals is critical. Developing continuing education resources dedicated to EC, in general, and UPA, in particular may prove a successful strategy. Exploring ways to disseminate information through the *Canadian Pharmacist's Letter* and circulars issued by the Canadian Pharmacists Association and/or the Ontario College of Pharmacies is also warranted.

The warning issued by Health Canada regarding the relationship between LNg-EC's efficacy and weight has placed pharmacists in a difficult position regarding what to recommend for heavier women. Recent evidence suggests that practices vary widely.^{7,24} Although UPA is more effective than LNg-EC in general, it may be an especially important option for heavier women. This may serve as important "hook" for discussing the complex information around weight and EC as well as for formulating Canada-specific "tier recommendations" modeled after efforts in other countries.²⁸⁻²⁹

Given the excellent safety profile,²⁶ the global trend in UPA provision is toward deregulation and OTC status.¹⁵ However, our results suggest that eventual deregulation of UPA in Ontario may prove challenging. Consistent with the history of LNg-EC in Canada,³⁰ most of the pharmacists we interviewed felt strongly that consultation should be required. Although some believed that UPA could (and should) eventually move to Schedule III status, these pharmacists were in the minority, a reflection less about the safety and efficacy of the drug and more about the perceived role of pharmacists. Future efforts to work toward deregulation should keep these dynamics in mind.

Finally, efforts to introduce UPA will have minimal impact if women are unaware of the option or if the drug is unaffordable. The introduction of UPA offers a window of opportunity to renew public education efforts around EC. Further, updating sexual education curricula, patient education materials, and sexual and reproductive websites to include the full range of available EC methods is a priority. Pharmacists will have a key role in these initiatives and our findings suggest they will welcome this responsibility and opportunity.

Limitations

This project has a number of limitations. First, our survey response rate was very low (14.2%) and with limited Francophone participation. Second, with the exception of one interview, our study was conducted prior UPA's introduction into the Canadian market for use as an EC. If we repeated our study in the post-marketing period, it is likely that knowledge of UPA would be greater. However, our findings do provide a baseline on which to ground future research. Finally, although reported intention to carry the product was high in both components of the study, our findings may not accurately reflect actual post-approval practices. Research assessing current pharmacy practices with respect to UPA in Canada would be of value.

Conclusion

The recent introduction of Ella® into the Canadian Health system marks an important milestone in providing women with comprehensive range of contraceptive methods. As frontline health care professionals, pharmacists will likely play a critical role in raising awareness of and promoting access to UPA within their communities. Engaging with pharmacists and supporting continuing education efforts appear warranted.

Acknowledgements

Andréanne Chaumont received the Queen Elizabeth II Graduate scholarship in science and technology and several grants from the University of Ottawa to support this thesis project. Dr. Foster's Endowed Chair in Women's Health Research is 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 would like to thank Drs. Raywat Deonandan and Karen Phillips for their feedback during various phases of this project. We would also like to thank Dr. Shelia Dunn and her team for providing us with their survey instrument and the team of volunteers who worked on this project. The conclusions and opinions expressed in this article are those of the authors and do not necessarily represent the views of the organizations with which the authors are affiliated or the funders.

References

1. Fisher W, Boroditsky R, Morris B. The 2002 Canadian contraception study: Part 1. *J Obstet Gynaecol Can* 2004;26(6):580-90.
2. Norman WV. A review of therapeutic abortions and related areas of concern in Canada. *J Obstet Gynaecol Can* 2012;34(11):1024-5.
3. Black A, Yang Q, Wen A, Lalonde A, Guilbert E, Fisher W. Contraceptive use among Canadian women of reproductive age: Results of a national survey. *J Obstet Gynaecol Can* 2009;31(7):627-640.
4. Foster AM, Wynn LL. Emergency contraception: The story of a global reproductive health technology. New York, NY: Palgrave Macmillan; 2012, p.3.
5. Eggertson L. Plan B comes out from behind the counter. *CMAJ* 2008;178(13).
6. Dunn S, Brown T, Alldred J. Availability of emergency contraception after its deregulation from prescription-only status: As survey of Ontario pharmacies. *CMAJ* 2008;178(4):423-24. doi: 1503/cmaj.070861.
7. Chaumont A, Foster AM. The not so over-the-counter status of emergency contraception in Ontario: A mixed-methods study with pharmacists. (Under review).
8. Trussell J. Emergency contraception: Hopes and realities. In *Emergency contraception: The story of a global reproductive health technology*. AM Foster & LL Wynn (Eds). New York, NY: Palgrave Macmillan, 2012, p.19-38.
9. Rosato E, Farris M, Bastianelli C. Mechanism of action of ulipristal acetate for emergency contraception: A systematic review. *Frontiers in Pharmacology* 2016;6(315):1-7.
10. Aiken AR, Trussell J. Recent advances in contraception. *F1000Prime Rep* 2014;6:113.
11. Glasier AF, Cameron ST, Fine PM, Logan SJS, Casale W, Van Horn J, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: A randomised non-inferiority trial and meta-analysis. *Lancet* 2010;375:555-62.
12. Benagiano G, von Hertzen H. Towards more effective emergency contraception? *Lancet* 2010;375(9714):527-28.
13. Product monograph for Ella. Actavis Specialty Pharmaceuticals Co. 2015.
14. HRAPharma. EllaOne®, http://www.hra-pharma.com/index.php/en/our_products/womens_health/emergency_contraception/ellaone; 2016 [accessed 18.03.16].
15. Italia S, Brand H. Status of emergency contraceptives in Europe one year after the European Medicines Agency's recommendation to switch ulipristal acetate to non-prescription status. *Public Health Genomics* 2016:1-8.
16. U.S. FDA Food and Drug Administration. FDA approves ella™ tablets from prescription emergency contraception. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222428.htm>; 2010 [accessed 18.03.16].
17. Canadian Pharmacist's Letter. New Drug: Ella (Ulipristal) 2015; New Drugs Approved by Health Canada in 2015, <http://canadianpharmacistsletter.therapeuticresearch.com/pl/NewDrugs.aspx?cs=&s=PLC&pt=21&yr=2015#molecular;2015> [accessed 25.05.16].
18. Kapp N, Abibol JL, Mathé H, Scherrer B, Guillard H, Gainer E, et al. Effect of body weight and BMI on the efficacy of levonorgestrel emergency contraception. *Contraception* 2014;91:91-104.

19. Gemzell-Danielsson K, Kardos L, von Hertzen H. Impact of bodyweight/body mass index on the effectiveness of emergency contraception with levonorgestrel: A pooled-analysis of three randomized controlled trials. *Curr Med Res Opin* 2015;31(12):2241-48.
20. Glasier A, Cameron ST, Blithe D, Scherrer B, Mathe H, Levy D, et al. Can we identify women at risk of pregnancy despite using contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception* 2011;84:363-67.
21. European Medicines Agency. Levonorgestrel and ulipristal remain suitable emergency contraceptives for all women, regardless of bodyweight, http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/07/news_detail_002145.jsp&mid=WC0b01ac058004d5c1; 2014 [accessed 24.05.16].
22. U.S. Food and Drug Administration. Plan B (0.75mg levonorgestrel) and Plan B One-Step (1.5 mg levonorgestrel) Tablets Information, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm109775.htm> [accessed 24.05.16].
23. Healthy Canadians. Emergency contraceptive pills to carry warnings for reduced effectiveness in women over a certain body weight, <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/38701a-eng.php; 2014> [accessed 24.05.16].
24. Vogel L. Rethink weight limits on morning after pill. *CMAJ* 2015;187(10):719-20.
25. Health Canada. Production information – ELLA, <http://webprod5.hc-sc.gc.ca/dpd-bdpp/info.do?code=92065&lang=eng ;2015> [accessed 25.05.16].
26. Levy DP, Jager M, Kapp N, Abitbol JL. Ulipristal acetate for emergency contraception: Postmarketing experience after use by more than 1 million women. *Contraception* 2014;89: 431-33.
27. Batur P, Cleland K, McNamara M, Wu J, Pickle S, EC Survey Group. Emergency contraception: A multispecialty survey of clinician knowledge and practices. *Contraception* 2016;93:145-152.
28. Kohn J, Nucatola DL. EU4U: Results from a pilot project integrating the copper IUD into emergency contraceptive care. *Contraception* 2016;94:48-51
29. Michie L, Cameron ST, Glaiser A, Larke N, Muir A, Lorimer A. Pharmacy-based interventions for initiating effective contraception following the use of emergency contraception: a pilot study. *Contraception* 2014;90:447-53.
30. Erdman JN. Canada: Competing frames of access and authority. In *Emergency contraception: The story of a global reproductive health technology*. AM Foster & LL Wynn (Eds). New York, NY: Palgrave Macmillan, 2012:57-78.

Chapter 5: Discussion

Our findings support the suggestion that women in Ontario still face a number of barriers in accessing emergency contraception (EC). The survey results and IDIs not only demonstrate existing barriers to EC access but also suggest ways to improve the current provision practices of EC in Ontario and Canada. This final chapter begins by integrating the results from the two articles along with other notable study findings. To continue, I explore the findings with regard to potential improvements to current emergency contraception services and the significance of our findings for future directions of EC services in Ontario. I then reflect on my positionality as a researcher and how it influenced this thesis project. I end with a statement of contribution and the conclusion of this thesis

5.1 Integration of results

A number of themes emerged from the two research articles: the lack of knowledge about modalities of EC other than LNG-ECPs, the belief that pharmacists play a critical role in health promotion and service delivery related to reproductive health, including EC, and the keen interest pharmacists have in providing high quality care. The Canadian pharmacy workforce describes high quality care as providing care that is clinically relevant and safe, promotes wellbeing, and has positive outcomes on the patient's overall health (Canadian Institute for Health Information [CIHI], 2012). As per their mandate, Canadian pharmacists are leaders in the development and maintenance of comprehensive and integrated health information that ultimately enables sound policy and improves health and health care (CIHI, 2012).

5.1.1 Knowledge, awareness and education

Findings presented in both articles highlight that knowledge of the most effective methods of EC, UPA and the Copper-T IUD, is significantly lower than knowledge of LNg-EC, the most widely used method in Ontario. Even though some gaps in pharmacists' knowledge exist with respect to LNg-EC, the results demonstrate that knowledge about service delivery of the method is mostly accurate. Our findings also demonstrated that knowledge of more effective methods was inaccurate and illustrates a clear lack of awareness. Yet, limited knowledge of UPA was expected as the medication was not registered for EC purposes at the time of data collection. UPA (Ella®) only entered the market in November 2015, thus lack of awareness about the method is considerable. Since IUDs have been used for post-coital pregnancy prevention for more than three decades (Foster & Wynn, 2012) we expected knowledge to be both greater and more accurate. More specifically our findings demonstrate that the efficacy of the IUD as EC was overwhelmingly underestimated. Consistent with our findings, the literature demonstrates that women seeking EC are not being offered the IUD as EC by health care professionals due to lack to awareness (Belden & Harper, 2012). Appropriate knowledge and awareness of the method is paramount to increase use of IUDs among women of reproductive age. Knowledge of pharmacists with respect to both IUD and UPA as a form of EC appears to be dependent on the pharmacist's individual practice.

Both the quantitative and qualitative results of this study highlighted that continuing education (CE) courses were repeatedly offered as a way to promote knowledge and awareness of all EC technologies. Our findings demonstrate that pharmacists are generally not aware of CE courses on EC, and the majority have never participated in a CE course about emergency contraception. Further, the recent registration of UPA into the Canadian health system provides a window of opportunity to update pharmacists on effective and available methods of EC (Product

monograph for Ella, 2015; Canadian Pharmacist's Letter, 2015). However, interest is significant and almost all survey participants (90%) would be interested in taking a CE course dedicated to EC. The high interest in CE training suggests that this could be an important avenue for increasing awareness about both new and existing EC modalities. Adequate education of pharmacists is a cornerstone in providing quality care. The need for continuing education courses about EC technologies offered to pharmacists on a regular basis (e.g. annually) appears warranted.

Further, based on our findings the current Ontarian pharmacy curriculum has not been recently updated and does not include information about UPA nor about the IUD as EC. Our findings suggest that a pharmacist's knowledge and awareness of EC is influenced by the pharmacy school he/she attended. In Ontario, three quarters of the pharmacist workforce was trained in the province (CIHI, 2012). However, both of the pharmacists who completed the interview in French were trained in pharmacy schools located in the province of Quebec. In the *Belle Province*, all EC medications are under the pharmacist's prescriptive supervision such that a mandatory consultation is required. Awareness and knowledge for those two pharmacists about the whole EC spectrum was significantly greater than those trained in Ontario. This suggests there may be some differences in pharmacist education and training between provinces (Ontario and Quebec specifically) and efforts to ensure incorporation of comprehensive EC information may result in better knowledge and practices.

5.1.2 Barriers in accessing EC

Consistent with Dunn and colleagues (2008) who found that 92% of Ontario pharmacies carried Plan B® after its deregulation from prescription to behind-the-counter status, our findings demonstrate that almost all surveyed pharmacies (93%) had in-stock availability of at least one

LNg-EC brand. Nevertheless, every community pharmacy should provide LNg-EC to ensure timely access to the medication. If a pharmacy currently does not have in-stock availability of LNg-EC, we believe that pharmacists must be able to refer women to a location where LNg-EC is accessible and available.

In Ontario, LNg-ECPs are registered as an over-the-counter product, therefore should be available directly from the shelf. However, as suggested by our findings, availability of Plan B® as an OTC product was surprisingly low and half of pharmacies (49%) in our study reported carrying LNg-ECPs behind-the-counter. Further, our findings demonstrated the apparent misinformation on behalf of Ontario pharmacists of the OTC status of LNg-ECPs. Over-the-counter availability promotes timely and equitable access to EC and privacy of use (Eggerston, 2008). Therefore, pharmacists must adhere to the Schedule III status of LNg-EC stipulating that it is an OTC medication. We believe that educational efforts focusing on the regulatory status of LNg-EC, and reminding pharmacists that consultation is not required, is justifiable.

We did not capture in-stock availability of other methods in the survey. However, results from the IDIs provided insights with respect to the availability of the IUD both for ongoing contraceptive and emergency contraceptive purposes. Consistent with the results of our study, in Canada IUDs as EC are generally not well promoted such they are often not carried by the Ontarian community pharmacy. Research is underway to determine if hormone-releasing IUDs can be used for post-coital pregnancy prevention (Turok et al., 2016). According to our respondents, the availability of hormone-releasing IUDs (e.g., Mirena® and Jaydess®) was significantly greater than the availability of Copper-T IUDs, despite the fact that the Copper-T IUD is the only type of device with demonstrated emergency contraceptive benefits (Trussell, 2012). The accessibility of a Copper IUD option is essential for the timely insertion of an IUD for

EC purposes due to the time-sensitive procedure. Thus the lack of availability of the Copper-T IUD in Ontario pharmacies acts as a major barrier to its use.

Further to the lack of consistent access to LNg-EC as an OTC product, our findings suggest that due to the regulatory reform that occurred over the last decade LNg-EC is not affordable to women. Plan B® and generic options (Next Choice® and Option 2®) are all costly medications, especially for financially vulnerable population such as adolescents, immigrants, and members of rural communities (Dunn et al., 2008; Eggerston, 2008; Singh, 2002). Further research is required to determine specific ways to offer LNg-EC at more affordable price.

Typically, UPA tends to be even more expensive than Plan B® (Mansour, 2009, Furedi, 2009). Given its recent introduction, it is difficult to determine the actual price of Ella® in Canada. To date, Ella® is not listed under the Ontario Drug Benefit program database (Ministry of Health and Long-Term Care, 2016), hence women without private insurance may need to pay out-of-pocket for the medication. With respect to the IUD, the high up-front cost of the device impedes some women from using it (Hauck & Costescu, 2015) In addition, the visit to a clinician required for the insertion of the device may prevent women from accessing this method given the time sensitive nature of the procedure. When examining our study findings, it is evident that the cost of emergency contraception modalities interferes with equal access to EC and is an area of concern among advocates of affordable EC technologies.

Finally, our two articles provide insight about the significant amount of questions that pharmacists typically ask women and the unnecessary recommendations and information that are provided before dispensing EC. Furthermore, in 2005 a number of advocates argued that a large number of pharmacies do not provide adequate spaces to protect the privacy and confidentiality of the clients seeking contraceptive products or counseling (Canadian Medical Association Journal [CMAJ], 2005). This lack of privacy acts as a considerable barrier to accessing EC

(Eggerston, 2008; Erdman, 2012). The literature indicates that some women are required to disclose sensitive information when they obtain medications such as EC, while others have indicated a fear of being judged when asking to obtain EC, especially if the medication is only available BTC (Kouri, 2006; Eggerston & Sibbald, 2005). However, our study results suggest that the lack of privacy is not a barrier for Ontario women since nearly all (94%) pharmacies self-declared that they provide a confidential space for consultation.

In addition, the majority of interviewees were women, which is roughly representative of the current Canadian pharmacy workforce (60%) (CIHI, 2012). Hope and colleagues (2012) found that female pharmacists were more likely to ask a larger number of questions and provide more information when delivering EC than their male counterparts. Although our sample was small, we identified the same trend. Lastly, consistent with the literature, our findings demonstrate that “gate-keeper” behaviors can ultimately prompt women to be reluctant to disclose all the required information, and ultimately leave the pharmacy without a potentially effective method to prevent a pregnancy, thereby negatively affecting women’s timely access to EC (Gainer et al., 2003).

5.1.3 Attitudes and roles of pharmacists

When exploring the path of EC’s rollout in Canada, the literature strongly demonstrates that some health care professionals are long-standing proponents of BTC status for progestin-only EC. Pharmacy bodies like the Canadian Pharmacists Association (CPhA) are known to be influential advocates of BTC status (CPhA, 1999). The belief that there is a need for a pharmacist’s intervention at point of sale transcended both articles and is characteristic of an authoritative frame over the delivery of EC. BTC advocates did not consider the need for consultation with a pharmacist as a barrier to EC access, but rather as a way to effectively

educate and counsel women on a range of reproductive health services. Consistent with the literature, BTC advocates also argue that the OTC sale of EC represents a missed opportunity for pharmacists to counsel potential patients about more effective methods of EC, use of an ongoing method of contraception, and risks of sexually transmitted infections (STIs) (Trussell & Guthrie, 2007; Aneblom, Lundborg, Carlsten, Eurenus, & Tydén, 2004).

5.1.4 Willingness of pharmacists to participate in and improve EC service delivery

Our interviews with pharmacists shed light on the roles that pharmacists could play in the case of a “same day pharmacy referral” initiative. This initiative would begin with the pharmacist performing a basic screening of a potentially eligible woman and would provide the device for insertion. Given that pharmacists deem themselves as integral to patient referrals (Downing, Payze, Doyle-Adams, & Gorton, 2011), they would refer the eligible patient to a physician for insertion immediately thereafter. A study assessing the acceptability of a task-sharing provision of contraceptives among Canadian pharmacists showed that pharmacists are highly open to participating and being responsible for a number of tasks associated with the prescription of contraceptives and patient follow-up (i.e. after the device has been inserted by a clinician) (Norman, Soon, Panagiotoglou, & Zed, 2015). The ACT-Pharm study demonstrated that pharmacists in British Columbia believe that their involvement is acceptable and feasible, and can be invaluable, especially in rural settings (Norman, Soon, Panagiotoglou, & Zed, 2015).

Findings from both articles illustrate that the introduction of UPA (Ella®) into the Canadian health care system is considered warranted by pharmacists; participants considered its introduction to be sound and legitimate. Pharmacists are willing to provide medications that are clinically relevant, safe, and have a positive impact on Canadian population health (CIHI, 2012).

Even if pharmacists were somewhat reluctant to introduce Ella® as an OTC product, interviewed pharmacists all acknowledged that UPA has the potential to address some of the current gaps in the EC service delivery of at both the provincial and national levels.

5.1.5 UPA and the IUD as first options for heavier women

Given the issue of the efficacy of Plan B® in heavier women raised in recent years, the introduction and promotion of more effective methods of EC, both provincially and nationally, is a priority for Canadian reproductive health care services (Eggerston, 2014). Consistent with the literature, our findings demonstrate that the weight issue is problematic in the delivery of EC to heavier women.

In order to address the issue, the FDA and EMA established tiered recommendations about efficacy such that UPA should be the first-line option for heavier women (Glasier et al. 2011; Batur et al., 2016). Currently, guidelines of the Canadian Contraception Consensus strongly recommend the use of UPA as the first choice to women with a BMI higher than 25kg/m² and use of the Copper-T IUD for those with a BMI higher than 30kg/m² (Black & Guilbert, 2015). Even if Copper-T IUDs and UPA are more appropriate options for heavier women, their limited availability makes implementation of this recommendation difficult. Given the prevalence of obesity in the Canadian society (Navaneelan & Janz, 2014), supporting efforts to increase the availability of all EC modalities as well as the awareness of tiered efficacy among pharmacists appears warranted.

5.2 Suggestions for improving access to EC in the Ontario context

This study aimed to determine priorities for improvement and concrete avenues for action. Our participants offered a number of suggestions as to how service delivery could be improved

and expanded. In addition to having import for service delivery in Ontario, these ideas may also have implications for practice in other areas of the country.

5.2.1 Education of the general population to promote use of EC

Participants outlined two ways to promote patient education about reproductive health, contraception, and EC. First, the Ontario educational system could be used to promote reproductive health knowledge. For instance, the Ontario's Ministry of Education updated its *Health and Physical Education Curriculum* in 2015 to include a *Human development and sexual health* ("sex ed") section which discusses a range of topics related to sexual health, including EC (Ministry of Education, 2016). The modification of the curriculum has the potential to address the need for education and lack of awareness about a range of reproductive health services in Ontario. Second, both pharmaceutical companies and pharmacists may be integral to the use of more effective EC methods by advertising the methods in strategic areas such as high schools and universities. Further, on multiple occasions, pharmacists have provided insights about educational talks to women of reproductive age, especially in smaller community settings.

5.1.2 Other ways services could be improved

Almost 20% of our respondents reported to "sometimes" using the Yuzpe method; a slightly higher proportion of respondents located in a rural area as compared to an urban area reported offering this method on at least some occasions. The Yuzpe method remains an important option, especially if other modalities are unavailable. Therefore, it appears justified to continue efforts to improve accessibility and availability of all EC modalities.

After analyzing our interview findings, it appears reasonable that in order to effectively implement an IUD as EC initiative, the OCP should develop a screening tool and

establish guidelines for a standardized referral process. Moreover, providing a contact list of available and willing providers to participate (including hospitals and clinics) is a leading suggestion proposed by our participants and would ultimately ease the overall process. Further, offering adequate training to pharmacists about the “same day pharmacy referral” appears warranted. Finally, exploring creative ways for pharmacists to dispense UPA and IUDs – such as through issuing prescribing authority for UPA or engaging pharmacists and physicians in collaborative practice agreements – could improve access to highly effective EC technologies.

5.3 Significance and future directions

The last study assessing the availability of emergency contraception in Ontario was published in 2008 and its findings were quickly outdated given the deregulation that occurred soon after its publication. Although a number of similar studies have been carried out in the United States and Canada (Aneblom, et al., 2004; Richman et al., 2012; Whelan, Langille & Hurst, 2012), our study continues the research of these previous studies and provides additional information about emergency contraception within Ontario that has not previously been documented. The ultimate goal is to provide insight into how the availability and service delivery of EC in Ontario could be improved in order for women to have easier and more timely access to effective EC technologies throughout the province. The results of the current project emphasize the need for improvement in a number of fields related to the service delivery of emergency contraception in Ontario. The recent introduction of UPA into the Canadian Health system and the lack of knowledge and awareness about EC technologies other than LNG-EC strongly support the development of continuing educational efforts.

Given the conceptual framework (PARIHS) used for this study, the dissemination of our findings is necessary to promote the adoption of our recommendations. We plan on disseminating

our findings through three avenues. First, we intend to submit three articles for publication from our study: Chapter 3 has been submitted to *Contraception*; Chapter 4 will be submitted to the *Journal of Obstetrics and Gynaecology Canada*; and we will develop a third article dedicated to the Copper-T IUD findings for submission to the *International Journal of Pharmacy Practice*. By publishing our findings in these three journals, we intend to promote knowledge and awareness of EC to pharmacy stakeholders including researchers, policy makers, and pharmacy advocates. Second, we intend to share a report of the findings with *Actavis*, the OCP and the CPhA. This report will outline some of the ways in which a CE course on EC could be developed and structured. Lastly, we have disseminated the findings of this study at academic conferences in Canada and the United States to reach non-pharmacy stakeholders.

5.4 Limitations

This study has a number of limitations. First, the survey component was characterized by a low response rate (14.2%). Surveys of this kind typically achieve response rates in the 30%-35% range. When we conceptualized the study two options were considered other than the mailing strategies. The first option was to recruit participants by email, inviting them to participate in an online survey. Although the literature indicates that distributing paper surveys by mail tends to yield a better response rate when performing research with health care professionals (Funkhouser et al., 2016), we cannot be sure whether distributing the survey by email would have resulted in a higher response rate. The second option was to use a designated list on the OCP website listing of Ontario pharmacists that are willing to participate in research; which contains more than 5,000 health professionals. We did not use this database because given its voluntary nature the OCP database is not representative of the Ontario pharmacy workforce. Listed pharmacists are likely oversaturated in research and may respond to research of personal interest.

Furthermore, the list does not mention the region where the pharmacist practices and thus would have complicated the creation of our current study sample given that regional information was integral to our study's criteria.

Although we purposely over-sampled community pharmacies located in Franco-Ontario communities, the response rate was especially low for the French component of the surveys. Unfortunately, we cannot draw any specific conclusions with respect to barriers that this community may experience when accessing EC. A replication of the study in French carried out in Francophone communities would be warranted to further explore EC service delivery in Franco-Ontario communities.

We also had no control over the environment in which the pharmacist/pharmacy representative completed the questionnaire. The survey instructions asked respondents not to consult additional information (such as text books, medication databases, or co-workers). After analyzing the results, we are confident that the pharmacists largely did not use any additional information given the clear gaps in knowledge with respect to all surveyed EC technologies. The responses are consistent with the existing literature although the survey results may reflect an over-estimation of knowledge and a skew toward best practices.

Finally, ulipristal acetate was approved shortly after data collection ended. Even though educational and promotional efforts targeting health professionals only started a few months' prior, these activities may have positively influenced pharmacists' knowledge.

5.5 Positionality as a researcher and reflexivity

Positionality and reflexivity are important to qualitative research. Positionality takes into account the influences that the researcher's identity and experiences have on their perspectives and interpretation of the data (Rose, 1997). Reflexivity is an active process where the researcher

acknowledges the interplay between his/her own biases, personal experiences, and identity on the analysis/perception of the data and the study's conclusion (Dowling, 2006).

As a pharmacy technician for nearly three years (in the province of Quebec) I have been exposed to a number of situations where a woman was seeking emergency contraception. Even though the regulations in Quebec and Ontario are different, I think that this experience provided me with great insight into the existing barriers surrounding EC service delivery. I often perceived the consultation with a pharmacist, which is required in Quebec, as a barrier for women and I found that these interactions were intertwined with shame and stigma. As a young adult this experience helped me understand the importance of providing safe, effective, and easily accessible EC to any woman who seeks it.

Even though I do not have a pharmaceutical background per se, my work experiences and educational background provided me with the knowledge to easily discuss emergency contraception with pharmacists. I felt confident while conducting the interviews and appreciated the trust relationships that emerged during the encounters.

Furthermore, the work I conducted in completion of my thesis convinced me that I want to dedicate my career as a physician to providing reproductive health care to women of all ages, especially those of reproductive age. I felt personally affected by the survey responses and the interviews I conducted throughout my Master's project. Through the process of memoing, I was able to capture the influences of participants' perspectives on my own perception of reproductive health services.

5.6 Statement of contribution

As the Principal Investigator, I completed this study in partial fulfillment of the requirements for the Master of Science in Interdisciplinary Health Sciences Program at the

University of Ottawa. I was responsible for working with a team of volunteers to coordinate the printing, packaging and mailing of survey packages. I conceptualized the study, data collection and data analysis. I also led the writing of the two research articles.

A team of volunteers (Emily Bent, Nada Jadal, Sarah Kiobali, Sophie Leduc, Sadam Payaf and Hadjar Saidi) was responsible for entering the results and transcribing the majority of English interviews. Josée Riel was responsible to coordinate along the printing of all survey packages and reminders at the *docUcenter* within the University of Ottawa.

Dr. Foster served as the supervisor for the project and contributed to and was responsible for reviewing all components of the project, including conceptualization, study design, data collection, analysis, and dissemination. She was responsible for assigning volunteers to the project and supervised the study team throughout the process.

5.7 Conclusion

In Canada, unintended pregnancy continues to be a major public health issue; unintended pregnancies represent more than one third of all pregnancies (Fisher et al., 2004). Further use of moderately effective contraceptive methods or non-use of contraception is a significant driver of unintended pregnancy. The wide availability of LNg-EC since the early 2000s has not been shown to significantly reduce the rate of unintended pregnancies. Accessibility and availability of the more effective method such as the Copper-T IUD and UPA is limited.

This study was the first to assess Ontario pharmacists' knowledge, attitudes and provision practices after the deregulation of LNg-EC from a Schedule II to a Schedule III product. As expected pharmacists were generally knowledgeable about LNg-EC. LNg-ECPs are widely available in Ontarian pharmacies but half of the pharmacies surveyed still carry the product behind-the-counter. Results from our study reveal that Ontario pharmacists have little to no

knowledge about other methods of EC such as UPA and the Copper-T IUD and overwhelmingly underestimate the efficacy of the latter modality. Continuing education initiatives for pharmacists and educational efforts focusing on the regulatory status of all EC methods appear warranted.

Pharmacists believe that more effective methods of EC should be introduced in Ontario (and in Canada); the introduction of Ella® into the Canadian Health system was supported by our participants. The introduction of Ella® is a significant milestone in providing a more effective method to Ontario women, especially for heavier women. The implementation of “a same day referral project” garnered great enthusiasm among pharmacists. As frontline health care professionals Ontario pharmacists are open to increasing their role in the community in order to increase timely access to effective methods of EC.

Bibliography

- Aiken, A.R., & Trussell, J. (2014). Recent advances in contraception. *F1000Prime Rep*, 6, 113.
- Aneblom, G., Lundborg, C. S., Carlsten, A., Eurenus, K., & Tydén, T. (2004). Emergency contraceptive pills over-the-counter: practices and attitudes of pharmacy and nurse-midwife providers. *Patient Education and Counselling*, 55(1), 129–135.
- Batur, P., Cleland, K., McNamara, M., Wu, J., Pickle, S., & EC survey Group. (2016). Emergency contraception: A multispecialty survey of clinician knowledge and practices. *Contraception*, 93, 145-152.
- Benagiano, G., & von Hertzen, H. (2010). Towards more effective emergency contraception?. *Lancet*, 375(9714), 527-528. doi: 10.1016/S0140-6736(10)60146-8.
- Belden, P., & Harper, C. C. (2012) The copper IUD for emergency contraception, a neglected option. *Contraception*, 85, 338-339.
- Birks, M., Chapman, Y., & Francis, K. (2008). Memoing in qualitative research: probing data and processes. *Journal of Research in Nursing*, 13(1), 68-75.
- Black, A., Yang, Q., Wen, S. W., Lalonde, A., Guilbert, E., & Fisher, W. (2009). Contraceptive use among Canadian women of reproductive age: Results of a national survey. *Journal of Obstetrics and Gynecology Canada*, 31(7), 627-640.
- Black, A., & Guilbert, E. (2015). Canadian Contraception Consensus (Part 1). *Journal of Obstetrics and Gynecology Canada*, 37(10), 936-938.
- Black, A., Guilbert, E., Hassan, F., Chatziheofilou, I., Lowin, J., Jeddi, M., ... Trussell, J. (2015) The cost of unintended pregnancies in Canada: Estimating direct cost, role of imperfect adherence, and the potential impact of increased use of Long-Acting Reversible Contraceptives. *Journal of Obstetrics and Gynecology Canada*, 37(12), 1086-97.
- Callegari, L. S., Darney, B. G., Godfrey, E. M., Sementi, O., Dunsmoor-Su, R., & Prager, W. S. (2014). Evidence-based selection of candidates for the levonorgestrel intrauterine device (IUD). *Journal of the American Board of Family Medicine*, 27(1), 26-33. doi:10.3122/jabfm.2014.01.130142.
- Canada Gazette. (2005). Regulatory impact analysis statement, Part II. 139, 857-871.
- Canadian Agency for Drugs and Technologies in Health. (2013). Ulipristal acetate (fibrystal) (5 mg tablets): CADTH, Common Drug Review.
- Canadian Institute for Health Information [CIHI]. (2012). Pharmacist Workforce, 2012 – Provincial/Territorial Highlights. pp. 2, 9-10.

- Canadian Medical Association Journal. (2005). Emergency contraception moves behind the counter. Editorial. *Canadian Medical Association Journal*, 172(7), 845.
- Canadian Pharmacists Association [CPhA]. (1999). Motion on emergency contraception. Retrieved from http://www.pharmacists.ca/content/hcp/Resource_Centre/
- Canadian Pharmacists Association [CPhA]. (2016). Pharmacy in Canada. Retrieved from <http://www.pharmacists.ca/pharmacy-in-canada/>
- Canadian Pharmacist's Letter. (2015). New Drug: Ella (Ulipristal); New Drugs Approved by Health Canada in 2015. Retrieved from <http://canadianpharmacistsletter.therapeuticresearch.com/pl/NewDrugs.aspx?cs=&s=PLC&pt=21&yr=2015#molecular; 2015>.
- Canadian Women's Health Network. (2005). Improving Access to Emergency Contraception. Women and Health Protection and Canadian Women's Health Network. Retrieved from <http://www.cwhn.ca/en/node/26942>
- Canwest News Service. (2008, May 16). Morning-after pill approved for over-the-counter sales. Retrieved from <http://www.canada.com/topics/news/story.html?id=eb9a322c-0b86-414c-8a28-a21d22c8c6a3>
- Chaumont, A, & Foster, A. M. (2016). The not so over-the-counter status of emergency contraception in Ontario: A mixed-methods study with pharmacists. (Under review).
- Cheng, L., Che, Y., & Gülmezoglu, A.M. (2012). Interventions for emergency contraception: Systematic review. *Cochrane Database*, doi : 10.1002/14651858.CD001324.pub4.
- Cleland, K., Zhu, H., Goldstuck, N., Cheng, L., & Trussell, J. (2012). The efficacy of intrauterine devices for emergency contraception: A systematic review of 35 years of experience. *Human Reproduction*, 27(7), 1994-2000. doi:10.1093/humrep/des140.
- Cohen, M.M., Dunn, S., Cockerill, R., & Brown, T.E. (2015). Emergency contraception: models to increase accessibility. *Journal of Obstetric and Gynaecology Canada*, 25(6), 499-504.
- Daniels, K., Daugherty, J., & Jones, J. (2014). Current contraceptive status among women aged 15-44: United States, 2011-2013. *National Health Statistics Report*, 173.
- Dowling, M. (2006). Approaches to reflexivity in qualitative research. *Nursing Research*, 13(3), 7-21.
- Downing, S. G., Payze, C., Doyle-Adams, S., & Gorton, C. (2011). Emergency contraception over-the-counter: Practices and attitudes of pharmacists and pharmacy assistants in far North Queensland. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 41, 527-531. doi: 10.1111/j.1479-828X.2011.01347.x

- Dunn, S., Brown T. E. R., & Alldred, J. (2008). Availability of emergency contraception after its deregulation from prescription-only status: a survey of Ontario pharmacies. *Canadian Medical Association*, 178(4), 423-424, doi: 1503/cmaj.070861.
- Dunn, S., & Cook, R. (2014). Medical abortion in Canada: Behind the times. *Canadian Medical Association Journal*, 186(1), 13-14. doi:10.1503/cmaj.131320.
- Eggerston, L. & Sibbald, B. (2005). Privacy issues raised over Plan B: Women asked for names, addresses, sexual history. *Canadian Medical Association Journal*, 173, 354-359.
- Eggerston, L. (2008). Plan B comes out from behind the counter. *Canadian Medical Association Journal*, 178, 1645-1646.
- Eggerston, L. (2014). Plan B emergency contraceptive may be ineffective for heavier women. *Canadian Medical Association Journal*, 186 (1), E21-22.
- Erdman, J. N. (2012). Emergency contraception: Hopes and realities. In *Emergency contraception: The story of a global reproductive health technology*. A.M. Foster and L.L. Wynn (Eds). New York, NY: Palgrave Macmillan, 57-78.
- European Medicines Agency. Levonorgestrel and ulipristal remain suitable emergency contraceptives for all women, regardless of bodyweight. Retrieved from http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/07/news_detail_002145.jsp&mid=WC0b01ac058004d5c1
- Fine, P. M. (2011). Update on Emergency contraception. *Advances in Therapy*, 28(2), 87-90.
- Fisher, W., Boroditsky, R., & Morris, B. (2004). The 2002 Canadian contraception study: Part 1. *Journal of Obstetrics and Gynecology Canada*, 26(6), 580-590.
- Foster, A. M., & Wynn, L. L. (Eds). (2012). *Emergency contraception: The story of a global reproductive health technology*. New York, NY: Palgrave Macmillan.
- Funkhouser, E., Vellala, K., Baltuck, C., Cacciato, R., Durand, E., McEdward, D., ... National Dental PBRN Collaborative Group. (2016). Survey Methods to Optimize Response Rate in the National Dental Practice-Based Research Network. *Evaluation & Health professions*, 1-27. doi: 10.1177/0163278715625738.
- Furedi, A. (2009). New emergency contraceptive method ellaOne – it is worth the price?. *Reproductive Health Matters*, 17(34) 187-188. doi: [http://dx.doi.org/10.1016/S0968-8080\(09\)34481-X](http://dx.doi.org/10.1016/S0968-8080(09)34481-X)
- Gainer, E., Blum, J., Toverud, E. L., Portugal, N., Tyden, T., Neshiem, B. I., ... Winikoff, B. (2003). Bringing emergency contraception over the counter: experiences of non-prescription users in France, Norway, Sweden and Portugal. *Contraception*, 68, 117-124.

- Gemzell-Danielsson, K., Kardos, L., von Hertzen, H. (2015). Impact of bodyweight/body mass index on the effectiveness of emergency contraception with levonorgestrel: A pooled-analysis of three randomized controlled trials. *Current Medical Research and Opinion*, 31(12),2241-2248.
- Glasier, A.F., Cameron, S.T., Fine, P.M., Logan, S.J.S., Casale, W., Van Horn J., ... & Gainer, E. (2010). Ulipristal acetate versus levonorgestrel for emergency contraception: A randomised non-inferiority trial and meta-analysis. *Lancet*, 375, 555-562.
- Glasier, A., Cameron, S. T., Bliithe, D., Scherrer, B., Mathe, H., Levy, D., ... Ulmann, A. (2011). Can we identify women at risk of pregnancy despite using contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception*, 84, 363-367.
- Harvey, G., & Kitson, A. (2016). PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implementation Science*, 11(33), 1-13. doi 10.1186/s13012-016-0398-2.
- Hauck, B., & Costescu, D. (2015). Barriers and misconceptions limiting widespread use of intrauterine contraception among Canadian Women. *Journal of Obstetrics and Gynaecology Canada*, 37(7), 606-16.
- Health Canada. (2015, July 30). Regulatory decision summary: MIFEGYMISO. Retrieved from http://hc-sc.gc.ca/dhp-mps/prodpharma/rds-sdr/drug-med/rds_sdr_mifegymiso_160063-eng.php.
- Health Canada. (2015). Production information – ELLA. Retrieved from <http://webprod5.hc-sc.gc.ca/dpd-bdpp/dispatch-repartition.do?lang=eng>.
- Healthy Canadians. (2014). Emergency contraceptive pills to carry warnings for reduced effectiveness in women over a certain body weight. Retrieved from <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/38701a-eng.php>.
- Hope, D. L., King, M. A., & Hattingh, H. L. (2012). Responses of pharmacy students to hypothetical refusal of emergency hormonal contraception. *International Journal of Pharmacy Practice*. 22, 155-58.
- HRA Pharma. (2014). Effect of weight on efficacy of emergency contraceptives: Conclusion of the referral initiated by the EMA. Retrieved from http://www.hra-pharma.com/index.php/en/you_are/media/effect_of_weight_on_efficacy_of_emergency_contraceptives.
- HRA Pharma. (2016). EllaOne®. Retrieved from http://www.hrpharma.com/index.php/en/our_products/womens_health/emergency_contraception/ellaone.
- Italia, S., & Brand, H. (2016). Status of emergency contraceptives in Europe one year after the

European Medicines Agency's recommendation to switch ulipristal acetate to non-prescription status. *Public Health Genomics*, 1-8.

Johnson, R. (2012, December 7th). Graphic: Abortion in Canada — almost 100,000 documented terminations in 2009. *National Post*, Retrieved from <http://news.nationalpost.com/news/canada/graphic-abortion-in-canada-almost-100000-documented-terminations-in-2009>.

Kapp, N., Abibol, J.L., Mathé, H., Scherrer, B., Guillard, H, ... & Ulman, A. (2014). Effect of body weight and BMI on the efficacy of levonorgestrel emergency contraception. *Contraception*, 91, 91-104.

Kohn, J., Nucatola, D.L. (2016). EU4U: results from a pilot project integrating the copper IUD into emergency contraceptive care. *Contraception*, 94, 48-51.

Kouri, R. P. (2006). Achieving reproductive rights: Access to emergency oral contraception and abortion in Quebec. In *Just Medicare: What's In, What's Out, How we Decide*, ed. C. Flood, 137-167. Toronto: University of Toronto Press.

Koyama, A., Hagopian, L., & Linden, J. (2013). Emerging options for emergency contraception. *Clinical Medicine Insights: Reproductive Health*, 7, 23-35. doi:10.4137/CMRH.S8145.

Levy, D.P., Jager, M., Kapp, N., & Abitbol, J.L. (2014). Ulipristal acetate for emergency contraception: Postmarketing experience after use by more than 1 million women. *Contraception*, 89, 431-433.

Mansour, D. (2009). EllaOne: A second-generation emergency contraceptive?. *Journal of Family Planning and Reproductive Health Care*, 35(4), 217. doi:10.1783/147118909789587141.

Michie, L., Cameron, S.T., Glaiser, A., Larke, N., Muir, A., & Lorimer, A. (2014). Pharmacy-based interventions for initiating effective contraception following the use of emergency contraception: a pilot study. *Contraception*, 90, 447-453.

Ministry of Education. (2016). Sex education in Ontario. Retrieved from <https://www.ontario.ca/page/sex-education-ontario>

Ministry of Health and Long Term Care. (2016). Which drugs do the programs pay for?. Retrieved from <https://www.healthinfo.moh.gov.on.ca/formulary/SearchServlet>

National Advisory Committee on Emergency Contraception (NACEC). (2003). National Advisory Committee on Emergency Contraception: Background. Retrieved from http://www.pharmacists.ca/content/about_cpha/whats_happening/cpha_in_action.

National Association of Pharmacy Regulatory Authorities. (2008, May 14). Drug schedules Notice Board re NDASAC Final Recommendations for: levonorgestrel, benzoyl peroxide, and famotidine. Retrieved from http://napra.ca/pages/Schedules/drug_schedules_notice_board.aspx.

- National Association of Pharmacy Regulatory Authorities (NAPRA). (2009). Drug Information Resources – Emergency contraception, 2009. Retrieved from http://napra.ca/pages/Practice_Resources/drug_information_resources.aspx?id=2141
- Navaneelan, T., & Janz, T. (2014). Adjusting the scales: Obesity in the Canadian population after correcting for respondent bias. *Health at Glance- Statistics Canada*, 82(624), 1-10.
- Norman, W. V. (2012). A review of therapeutic abortions and related areas of concern in Canada. *Journal of Obstetrics Gynaecology of Canada*, 34(11), 1024-1025.
- Norman, W. V., Soon, J. A., Panagiotoglou, D., Albert, A., & Zed, P. J. (2015). The acceptability of contraception task-sharing among pharmacists in Canada – the ACT-Pham study. *Contraception*, 92, 55-61.
- Plan B. (2016). What to expect - 2016 Paladin Labs. Retrieved from <http://www.planb.ca/what-to-expect.html>.
- Product monograph for Ella. (2015, January). Actavis Specialty Pharmaceuticals Co. Mississauga.
- Raymond, E.G., Creinin, M.D., Barnhart, K.T., Lovvorn, A.E., Rountree, W., & Trussell, J. (2000). Meclizine for prevention of nausea associated with emergency contraceptive pills: a randomized trial. *Obstetrics & Gynecology* 95, 271-277.
- Raymond, E. G., Trussell, J., & Polis, C. B. (2007). Population effect of increased access to emergency contraceptive pills, *American College of Obstetrics & Gynecology*, 109(1), 181-188.
- Richman, A. R., Daley, E. M., Baldwin, J., Kromey, J., O'Rourke, K., & Perrin, K. (2012). The role of pharmacists and emergency contraception: are pharmacists' perceptions of emergency contraception predictive of their dispensing practices?. *Contraception*, 68, 370-75.
- Rosato, E., Farris, M., & Bastianelli, C. (2016). Mechanism of action of ulipristal acetate for emergency contraception: A systematic review. *Frontiers in Pharmacology*, 6(315), 1-7.
- Rose, G. (2007). Situating knowledge: positionality, reflexivities and other tactics. *Progress in Human Geography*, 21(3), 305-20.
- Sivin, I. (2007). Utility and drawbacks of continuous use of copper T IUC for 20 years. *Contraception*, 74(6), 1102-07.
- Singh, V. (2002). Rural income disparities in Canada: A comparison across the provinces. *Rural and small town Canada analysis Bulletin*, 3(7), 1-18.
- 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. *Canadian Medical Association Journal*, 172, 878-883.

Task Force on Postovulatory Methods of Fertility Regulation. (1998). Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet*, 352(9126), 428-33.

Trussell, J., Rodríguez G., & Ellertson, C. (1999). Updated estimates of the effectiveness of the Yuzpe regimen of emergency contraception. *Contraception*, 59, 147-51.

Trussell, J., & Guthrie, K. A. (2007). Talking straight about emergency contraception. *Journal of Family Planning and Reproductive Health Care*, 33, 139-142.

Trussell, J. (2012). Emergency contraception: Hopes and realities. In *Emergency contraception: The story of a global reproductive health technology*. A.M. Foster and L.L. Wynn (Eds). New York, NY: Palgrave Macmillan, 19-38.

Trussell, J., Raymond, E.G., & Cleland, K. (2015). Emergency contraception: A last chance to prevent unintended pregnancy.

Turok, D. K., Sanders, J. N., Thompson, I. S., Royer P. A., Egeebrotten, J., & Gawron, L. M. (2016). Preference for and efficacy of oral Levonorgestrel for emergency contraception with concomitant placement of Levonorgestrel IUD: a prospective cohort study. *Contraception*, 93, 526-532.

U.S. FDA Food and Drug Administration. (2010). FDA approves ella™ tablets for prescription emergency contraception. Retrieved from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222428.htm>.

U.S. Food and Drug Administration. Plan B (0.75mg levonorgestrel) and Plan B One-Step (1.5 mg levonorgestrel) Tablets Information. Retrieved from <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm109775.htm>.

Vogel L. Rethink weight limits on morning after pill. *CMAJ* 2015;187(10):719-720.

von Hertzen, H., Piaggio, G., Ding, J., Chen, J., Song, S., Bártfai, G., ...Peregoudov, A. (2002). A. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: A WHO multicentre randomised trial, *Lancet*, 360(1948), 1803-10.

Weir, E. (2003). Preventing pregnancy: a fresh look at the IUD. *Canadian Medical Association Journal*, 169(6), 585.

Whelan, A. M., Langille, D. B., & Hurst, E. (2013). Nova Scotia pharmacists' knowledge of, experiences with and perception of factors interfering with their ability to provide emergency contraceptive pill consultations. *International Journal of Pharmacy Practice*, 21, 314-321. doi: 10.1111/ijpp.12017

Wiebe, E. (2013). Contraceptive practices and attitudes among immigrant and nonimmigrant women in Canada. *Canadian Family Physician*, 59, e451-e455.

Appendix A: Health Canada warning included on Plan B® package

*plan B® is less effective in women weighing 165 lbs (75 kg) or more and not effective in women weighing more than 176 lbs (80 kg). If your weight is 165 lbs (75 kg) or more, ask your healthcare professional for advice on alternative methods of emergency contraception.

Appendix B: REB approval letter - Component I

File Number: H03-14-20

Date (mm/dd/yyyy): 07/03/2014



Université d'Ottawa **University of Ottawa**
Bureau d'éthique et d'intégrité de la recherche Office of Research Ethics and Integrity

Ethics Approval Notice Health Sciences and Science REB

Principal Investigator / Supervisor / Co-investigator(s) / Student(s)

<u>First Name</u>	<u>Last Name</u>	<u>Affiliation</u>	<u>Role</u>
Angel	Foster	Health Sciences / Others	Principal Investigator
Andréanne	Chaumont	Health Sciences / Others	Project Coordinator

File Number: H03-14-20

Type of Project: Professor

Title: Assessing the emergency contraception knowledge, attitudes, and provision patterns of pharmacists in Ontario: A provincial survey

Approval Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
07/03/2014	07/02/2015	Ia

(Ia: Approval, Ib: Approval for initial stage only)

Special Conditions / Comments:
N/A

1

550, rue Cumberland, pièce 154 550 Cumberland Street, room 154
Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada
(613) 562-5387 • Téléc./Fax (613) 562-5338

www.recherche.uottawa.ca/deontologie/ www.research.uottawa.ca/ethics/

Appendix C: REB approval letter - Component II

File Number: 02-15-12

Date (mm/dd/yyyy): 03/06/2015



Université d'Ottawa **University of Ottawa**
Bureau d'éthique et d'intégrité de la recherche Office of Research Ethics and Integrity

Certificate of Ethics Approval Social Science and Humanities REB

Principal Investigator / Supervisor / Co-investigator(s) / Student(s)

<u>First Name</u>	<u>Last Name</u>	<u>Affiliation</u>	<u>Role</u>
Angel	Foster	Health Sciences / Interdisciplinary School	Supervisor
Andréanne	Chaumont	Health Sciences / Interdisciplinary School	Student Researcher

File Number: 02-15-12

Type of Project: Master's Thesis

Title: Exploring the knowledge, attitudes, and practices of pharmacists in Ontario: A mixed-methods study dedicated to emergency contraception

Approval Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
03/06/2015	03/05/2016	Ia

(Ia: Approval, Ib: Approval for initial stage only)

Special Conditions / Comments:
N/A

1

550, rue Cumberland 550 Cumberland Street
Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada
(613) 562-5387 • Téléc./Fax (613) 562-5338
<http://www.recherche.uottawa.ca/deontologie/> <http://www.research.uottawa.ca/ethics/index.html>