

**Emergency Contraception in Brazil:
Exploring the Journey of the Medication and Current Availability**

Thesis

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Abstract

Brazil's healthcare system currently offers a wide range of contraception options and emergency contraception (EC) has been among them since the late 1990s. Abortion, however, is severely legally restricted and high rates of both teenage pregnancy and unsafe abortion plague the country. Given this context, levonorgestrel emergency contraceptive pills (ECPs) could play a significant role women's health and lives. This research aimed to examine the journey of this medication in Brazilian society and assess its availability in three cities located in different regions of the country. To address these research objectives, I performed a textual and discourse analysis of written materials as well as a mystery client study. Despite the wide availability of ECPs in retail pharmacies, I found that religious beliefs and conservative values still hinder accessibility. The results suggest that awareness raising campaigns are needed and long overdue. However, there is also a need to employ novel strategies for improving access and engaging healthcare professionals. Further research and advocacy related to women's reproductive health and rights in general, and EC in particular, appears warranted.

Resumé

Le système de santé brésilien offre actuellement un large éventail d'options de contraception et la contraception d'urgence (EC) figure parmi celles-ci depuis la fin des années 1990. Toutefois, l'avortement est sévèrement restreint par la loi et les taux élevés de grossesses ainsi que d'avortements chez les adolescentes à risque pèsent sur le pays. Dans ce contexte, les pilules contraceptives d'urgence (PCU) au lévonorgestrel pourraient jouer un rôle important dans

la vie des femmes, notamment au niveau de leur santé. Cette recherche visait à examiner le parcours de ce médicament (PCU) dans la société brésilienne et à évaluer sa disponibilité dans trois villes situées dans différentes régions du pays. Pour répondre à ces objectifs de recherche, j'ai effectué une analyse textuelle et discursive de documents écrits ainsi qu'une étude de client mystère. Malgré la grande disponibilité des PCU dans les pharmacies de détail, j'ai constaté que les croyances religieuses et les valeurs conservatrices entravent encore à l'accessibilité. Les résultats suggèrent que des campagnes de sensibilisation sont nécessaires et attendues depuis longtemps. Cependant, il est également nécessaire d'utiliser de nouvelles stratégies pour améliorer l'accès et l'engagement des professionnels de la santé. La recherche et le plaidoyer en faveur de la santé génésique ainsi que des droits des femmes en général, et de la CE en particulier, semblent justifiés.

Resumo

Atualmente, o sistema de saúde do Brasil oferece uma ampla gama de opções de contracepção e a contracepção de emergência (EC) está entre elas desde o final dos anos 90. O aborto, no entanto, é severamente restrito por lei penal, de forma que altas taxas de gravidez na adolescência e aborto inseguro flagelam o país. Dado este contexto, as pílulas anticoncepcionais de emergência que contém levonorgestrel (ECPs) poderiam desempenhar um papel significativo na saúde e na vida das mulheres. Esta pesquisa teve como objetivo analisar a trajetória dessa medicação na sociedade brasileira e avaliar sua disponibilidade em três cidades localizadas em diferentes regiões do país. Para abordar esses objetivos de pesquisa, realizei uma análise textual, bem como uma pesquisa de campo observacional como cliente oculto. Apesar da ampla disponibilidade de ECPs em farmácias de varejo, descobri que crenças religiosas e valores

conservadores ainda impedem a acessibilidade. Os resultados sugerem que campanhas de sensibilização são muito necessárias. No entanto, há também a necessidade de empregar novas estratégias para melhorar o acesso e envolver os profissionais de saúde. Há muitas razões para aprofundar a pesquisa e a advocacia relacionadas com a saúde reprodutiva das mulheres em geral, e CE em particular.

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List of acronyms and abbreviations

ANVISA	Agencia Nacional de Vigilância Sanitária
CLAE	Consórcio Internacional de Anticoncepção de Emergência
EC	Emergency contraception
ECPs	Emergency contraceptive pills
IBGE	Instituto Brasileiro de Geografia e Estatística (Brazilian Institute of Geography and Statistics)
ICEC	International Consortium for Emergency Contraception
IUD	Intrauterine device
OCs	Oral contraceptives
OCPs	Oral contraceptive pills
OTC	Over-the-counter
PAISM	Programa de Atenção Integral à Saúde da Mulher
PNAISM	Política Nacional de Atenção Integral à Saúde da Mulher
STIs	Sexually transmitted infections.
SUS	Unified Health System (Sistema Unico de Saude)

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Chapter 1 – Introduction

1.1 Background: Brazil and the Unified Health System

Brazil is a geographically large middle-income country located in South America. According to the Brazilian Institute of Geography and Statistics (Instituto Brasileiro de Geografia e Estatística, IBGE), in 2016 Brazil's population was over 206 million, including 104 million women (IBGE, 2016). Hastings-Asaturian (2004) explains that Brazil is a “third world country,” with extremes of both wealth and poverty. The wealth gap between the rich and the poor is significant: approximately 10% of the Brazilian population owns more than 51% of the country's wealth. According to the United Nations Development Program (2014), the country has a human development index of 0.755, indicating medium-level development.

The national healthcare system in Brazil is the Sistema Unico de Saude (SUS), which in English translates to the Unified Health System. Before the 1990s, access to healthcare services in Brazil was mainly limited to urban centers. In the 1990s, after the creation of SUS, the federal government embarked on a proactive effort to enhance healthcare access in rural areas as well as in poorer and less productive regions of the country. Consequently, less privileged populations in Brazil depend heavily on SUS for health services.

This system, which is supported mainly by the federal government, comprises a network of both public and private medical facilities. As an example of this duality, the system includes both public and private pharmacies. The public facilities dispense medications free-of-charge but require a prescription from a physician based in a clinic or hospital. These facilities are largely underfunded and routinely experience supply chain challenges. The private pharmacies are, according to Pereira and Freitas (2008), similar to the retail drugstores of North America regarding

pharmaceutical care and the pharmacy's role in the health system but as a rule, they do not receive government funds. The latter are the focus of this study.

SUS was officially established in 1988 as part of the constitution that was promulgated the same year (Ferreira, Souza, Lima, & Braga, 2010). Prior to the creation of the SUS, the healthcare system in Brazil was heavily privatized; free and low-cost services were limited to a small number of charitable institutions. This led to significant access disparities that negatively impacted informal workers, rural populations and farm workers, and the unemployed (Floss, 2015).

Today, most health-related products available through SUS public or private facilities must go through a registration process before becoming available to the population. The regulatory agency responsible for this process is ANVISA (Agencia Nacional de Vigilância Sanitária). After a due assessment for safety and efficacy, the product receives approval and is available directly to the population through the private sector or distributed free-of-charge through the government. However, distribution and availability of each product depends on its inclusion in specific health policies. These policies are periodically developed, administered, and revised by the federal government through the Ministry of Health but then may be further adapted by governments at the state and municipality levels (Ferreira et al., 2010). Ostensibly, this flexibility allows different regions to execute policies more efficiently and tailor services to different regional needs (Borges, OlaOlorun, Fujimori, Hoga, & Tsui, 2015).

However, despite the important role of ANVISA in the market regulation of health products, no public policies compel the private sector to maintain stocks of these products. Therefore, free market pressures (including demand and profit) as well as other cultural values may influence product availability. Although these overarching dynamics shape all medicines and health products approved in Brazil, there are specific implications for emergency contraception.

1.2 Reproductive Health in Brazil

Historically, women's health in Brazil has largely centered on pregnancy and childbirth. The oral contraceptive pill (OCP) arrived in Brazil in 1962, just two years after its approval by the US Food and Drug Administration. In the mid-1990s, the Brazilian government incorporated emergency contraception into the national family planning guidelines as well as sexual assault treatment programs. The establishment of the National Commission of Population and Development in 1995 as well as the enactment of the Family Planning Law in 1996 also marked milestones in the creation of reproductive health and planning policies for Brazilian citizens (Santos, Borges, Chofakian, & Pirotta, 2014).

Those advances were important considering that before SUS health policies in Brazil did not mention family planning and made only minimal reference to women's health more generally (Faúndes, Távora, Brache, & Alvarez, 2007). During the years of the conservative and dictatorial military government (1964–1986), the Brazilian Congress was dissolved and free speech restricted (Ferreira et al. 2010). Consequently, organized civil groups struggled to disseminate any kind of information, including information about new contraceptive methods.

In 1984, the first dedicated women's health program was proposed (Programa de Atenção Integral à Saúde da Mulher (PAISM)). PAISM promised to broaden the focus of women's health to issues outside of the narrow pregnancy and childbirth context. However, the actual implementation of the program was very gradual, as was the development of the SUS itself (Borges et al., 2015). Despite that, women's desire to prevent pregnancy was pronounced and Brazil witnessed a significant decline in the total fertility rate in the 1970s and 1980s (Borges, Tsui, Fujimori, & Hoga, 2016). For instance, in 1996, 34 years after the introduction of the OCP,

oral contraceptives were the most popular contraceptive method in Brazil, followed by the female sterilization (BEMFAM, 2004).

In the second half of the 1990s, Brazilian policies related to women's health gained new traction and two bills about family planning and sexual violence were approved in 1996 and 1998, respectively. Heavily influenced by the International Conference on Population and Development in Cairo (1994) and the Fourth World Conference on Women in Beijing (1995), these policies affirmed the importance of reproductive and sexual health (Santos, Borges, Chofakian, Pirotta, 2014; Alano, Costa, Miranda, Galato, 2012; Hardy, Duarte, Osis, Arce, Possan, 2001). The most recent policy change occurred in 2004, when the PNAISM (Política Nacional de Atenção Integral à Saúde da Mulher) called for more evidence-based responses to women's health needs and efforts to address the evident socioeconomic and geographic disparities in services. PNAISM also called for greater social participation by women, noting the relationship between women's status and health (Brazil's Special Secretary of Womens' Policies, 2015).

Currently, Brazil boasts a strong mixture of contraceptive methods covered under the SUS system (Ferreira et al., 2010). Oral contraceptive pills, hormonal injections, diaphragms, male and female condoms, and emergency contraception are available through Brazilian public services and through private retail pharmacies. The copper-T intrauterine device (IUD) and sterilization procedures are also covered through the public health system (Borges et al., 2015). However, SUS does not cover the progestin-releasing IUD, contraceptive implants, or hormonal patches and rings; these methods are only available through the private sector. As a result, access to contraceptive products is uneven, particularly for newer technologies (Santos et al., 2014). Logistical barriers, funding challenges, and slow uptake of evidence-based policies and protocols offer possible explanations for this uneven access.

Despite the many challenges and shortcomings, Guilhem and Azevedo (2007) assert that PAISM represents a significant advancement in reproductive health in Brazil. Further, Brazilian law also advocates for universal access to the family planning methods (Borges et al., 2015). However, even though prenatal care is crucial for women's reproductive health, Brazilian women have difficulty accessing services that require several consultations (Ferreira et al., 2010). Further, abortion is severely legally restricted. Brazilian criminal law prohibits abortion except in cases when the pregnancy threatens the life of the woman, originated from rape, or includes a diagnosis of fetal anencephaly. Therefore, unsafe abortion is common and is a major contributor to maternal mortality in the country (McCallum, Menezes, Reis, 2016).

1.3 Emergency Contraception

Emergency contraception (EC) refers to medications and devices that are used post-coitally to reduce the risk of pregnancy and represent a last chance for individual women to prevent pregnancy (Trussell, 2012). The copper-T IUD is the most effective method of EC, but is rarely used for this indication (Trussell, 2012). Several different pill-forms of EC are also available and contain a range of active ingredients. Anti-progestin pills include low-dose mifepristone and ulipristal acetate (Trussell, 2012). Because mifepristone is primarily used to induce early abortion (at higher doses and once pregnancy is established) its adoption as an emergency contraception has been muted; the drug is banned in Brazil. Ulipristal acetate (UPA) is a second generation emergency contraceptive and has been registered in Brazil (brand name, ULIP®) since December 2015. No information has been published on the availability or use of UPA in Brazil and this is not the focus of the current study. Combined hormonal pills – that is, pills containing both an estrogen and a progestin – can also be used post-coitally to prevent pregnancy. Commonly referred

to as the Yuzpe method, this modality of emergency contraception typically involves creating a regimen with available oral contraceptive pills, although there have historically been dedicated products (Trussell, 2012). In order to minimize the side effects of nausea and vomiting, the medication is given in two doses taken 12 hours apart and can be taken when more effective methods are not available. Because OCPs are available throughout Brazil so too is the Yuzpe method.

However, the most common form of emergency contraception worldwide is the progestin-only emergency contraceptive pill (ECP); it is this form of EC that is the focus of the study. The progestin-only regimen consists of 1.5mg of levonorgestrel taken within five days of unprotected or under-protected intercourse. This can be taken as a single 1.5 mg dose or two 0.75mg doses taken 12 hours apart; the former is recommended because of patient compliance (Trussell, 2012). Because the primary mechanism of action is to delay or inhibit ovulation, progestin-only EC is more effective when taken in the first 24 hours after the sexual event and can reduce the risk of pregnancy by up to 89% (Trussell, 2012).

According to the World Health Organization (WHO), there are no risks to using progestin-only ECPs that outweigh the benefits and there are no absolute contraindications to use. Progestin-only ECPs have not been associated with any deaths or serious complications (Trussell, 2012). The most common side effects – which are transient – are nausea, vomiting, abdominal pain, headaches, dizziness and fatigue. Progestin-only may also influence the length of the menstrual cycle or the patterns of the menstrual bleeding, but inter-menstrual bleeding is not a common side effect (Trussell, 2012).

A global body of research has established the safety and efficiency of emergency contraception, which has now been used for nearly 30 years (Figueiredo, 2004; Costa, Ferraz,

Souza, Silva, & Almeida, 2008). Indeed, progestin-only EC is included on the WHO's Essential Medicines List (EML) and is specifically included on the national EMLs of 61 countries (ICEC, 2016). Nevertheless, progestin-only EC is underutilized by women in Latin America and thus its ability to help prevent mortality and morbidity related to unplanned pregnancies and unsafe abortion in nations where abortion is restricted has not been fully realized (Souza & Brandão, 2009).

1.4 Emergency contraception in Brazil

According to Santos et al. (2014), the contraceptive prevalence rate in Brazil is approximately 80%. However, nearly half (44%) of all pregnancies are unintended. This suggests that there is significant contraceptive failure and/or inconsistent use of contraception and thus progestin-only ECPs could play an important role in the Brazilian context.

ANVISA approved a levonorgestrel-based emergency contraception product for prescription sales in 1999 (Faúndes et al., 2007). In the same year, progestin-only ECPs were incorporated into the retail pharmacy sector and the public health system. ANVISA has also approved the copper-T IUD for use as a post-coital contraceptive method. Based on the 2006 National Survey of Demography and Health of Children and Women (PNDS), Souza & Brandão (2012) suggests that progestin-only EC was the third most used contraceptive method among self-identified single women and the fifth most used method among those who identified as having a partner. However, other studies have reported ever use of progestin-only EC ranging from 11% to 80% (Souza & Brandão, 2009; Brazil, Ministry of Health 2009). A number of studies suggest that misinformation among providers and potential users and socio-religious opposition may influence use of emergency contraception in Brazil (Souza 2008). However, little research has

investigated the availability of EC in Brazil. Furthermore, a comprehensive history of the process by which ECPs were approved and later incorporated into the Brazilian health system has not been conducted.

This overall context motivated this research study. This research project aims to shed light on the journey of EC in Brazil and explore the complex intersection of policy, regulatory, advocacy, and opposition factors that have influenced its incorporation into the health system. Furthermore, through mystery client visits to retail pharmacies in three different cities, this project seeks to understand better private sector availability of ECPs.

1.5 Research questions

1. What are the factors and dynamics that shaped EC's incorporation into the Brazilian health system over the last two decades?
2. What is the current availability of progestin-only ECPs in retail pharmacies in different areas of the country and what information do pharmacists provide to potential users?
3. What avenues might be explored to improve the availability and accessibility of ECPs in Brazil?

1.6 Outline of thesis

This thesis is divided into five chapters. Chapter 1 introduces to the overall project. This chapter introduces the reader to the Brazilian context and emergency contraception. In addition, this chapter situates the current research project within the body of existing literature and articulates the research questions. It also highlights the background of the problem, leading to the research rationale and significance and the research questions.

Chapter 2 describes the methods used for this research. This chapter begins with an overview of the purpose of the research, theoretical framework, and study design. It then details the two components of the project: the textual and discourse analysis and the mystery client study. After providing information about both data collection and analysis, the chapter ends with a discussion of ethical considerations.

The following two chapters present the results of the project. Chapter 3 focuses on the findings from the first study component and offers a narrative of the journey of EC in Brazil. Chapter 4 consists of an article that presents the results of the mystery client study. This article was published in *Contraception* in 2016 and conforms to the standards of that peer-reviewed journal.

Finally, Chapter 5 discusses the results of the overarching study. Using theoretical and conceptual lenses, this chapter integrates the findings from both study components and discusses the implications of the finding and recommendations for further research and action. This last chapter also discusses the positionality and reflexivity of the researcher, as well as the limitations of the project.

Chapter 2: Methods

2.1 Nature and theoretical framework of the study

This study is qualitative in nature. That is, the data collection and the focus of the analysis is not to quantify and generalize, but rather to explore meaning and understand phenomena (Golafshani, 2003). Moreover, action research serves as the theoretical foundation for this project. Specifically, this project is derived from and structured as a practical action research and follows an interpretivist research paradigm (Master, 1995; Grundy, 1982).

2.2 Research design

This is an observational study. Therefore, it assumes a minimum intervention from the researcher, myself, during data collection. The research is comprised of two components. One of them is a text and discourse analysis, using original research source material both physical and online, in order to describe the factors that shaped the history of incorporation of emergency contraception in Brazil's healthcare system. The second is a mystery client study in three cities of Brazil to determine the availability of ECPs and identify strategies for improving ECP availability and accessibility. Although the research project has two distinct components, in the last phase of the analytic process I integrated the findings.

2.3 Component 1: Textual and discourse analysis

The objective of this phase of the study was to identify and discuss the factors that shaped EC's incorporation into the Brazilian health system. The main aspects examined included a history on the introduction of emergency contraception, the current regulatory status of the progestin-only drug, public debates and discussions on emergency contraception, major lessons learned and

priorities for moving forward. The study also intended to identify the key players in the introduction of emergency contraception. Finally, through this component of the project I aimed to explore the way discussions or debates on emergency contraception have been framed as well as the responses from human rights groups, the medical community, religious leaders, public policy makers, the media, and politicians on introduction of emergency contraception. The methodological approach and the specific issues examined were modeled on the individual country chapters in *Emergency contraception: The birth of a global reproductive health technology* (Foster & Wynn, 2012). The guidelines used to explore the history and evolution of EC in Brazil are in Appendix B.

Data collection procedures

The data used in this component came from multiple sources, almost all of which were in Portuguese. To collect relevant data, I visited archives, libraries, and individual organizations in Brazil. These visits happened in February 2016 in Brasilia, Brazil, following the end of the fieldwork. Retrieval of media articles required both online searches as well as visits to libraries and newspaper offices. I also searched for materials using online databases, which included PUBMED, SCOPUS, Google Scholar, as well as thesis and dissertations available in Brazil. This online search occurred in March and April 2016. My searches were in both English and Portuguese and focused on emergency contraception, contraception, family planning, reproductive health, and women's health and I paid specific attention to issues related to availability, accessibility, acceptability, knowledge, attitudes, practices, and behaviors.

To examine this history, I consulted a range of sources. The sources included policy documents, regulatory decisions, and standard of care guidelines. Moreover, I reviewed published research (peer reviewed and grey literature), reports and websites of advocacy organizations and

opposition groups, and the public speeches and writings (for example op-eds and blogs) of prominent individuals in Brazilian society (politicians, providers, religious leaders, and activists). Finally, I reviewed media accounts—both print and online—to explore the ways in which EC was covered during different phases of its journey. Following data collection, I synthesized and organized these data by domains of inquiry, considering both textual (content) and discourse (meaning behind the content) analysis.

Data analysis procedures

Textual analysis refers to a method by which the researchers collect information on the way humans understand the world (Creswell, 2013). It is a technique whereby the investigators aim at understanding how members from a given culture understand themselves. According to Frey, Botan and Kreps (1999), textual analysis deals with describing and interpreting the attributes of visual or recorded messages. The key goal of textual analysis is to provide a description of the structure, content, and functions present in messages within texts. In using this method, it was important for me to select texts suitable for exploring emergency contraception, acquiring the appropriate texts, as well as properly determining the best method of analyzing the texts.

Specifically, I performed content and textual analyses because this approach allowed me to determine, analyze, and enumerate occurrences of particular messages as well as the features of messages within the identified texts. In this investigation, content analysis involved identification and analysis of emergency contraception messages within various texts. This method is unobtrusive since the investigator studies existing texts rather than collects data to produce texts. In textual analysis, the researcher explores the frames and accuracy of the revealed “truth”. In this context, I sought to comprehend how representations of emergency contraception take place, the underlying assumptions of those representations, and the meaning of these revelations in the

Brazilian context. By analyzing and interpreting the discourses used to define, describe, and frame emergency contraception, I sought to understand the journey of the medication, focusing on the major changes in the regulatory status of ECPs, national-level case-building processes, the frames and changes in public narratives, debates, and discussions over time, and the inclusion of emergency contraception in national norms and guidelines.

2.4 Component 2: Mystery client study

To understand the current availability of ECP in Brazil, the second component of the thesis was a mystery client survey focused on the retail pharmacy sector. The mystery-client methodology involves a researcher seeking services in the assumed role of a client. The objective is to evaluate the provision of services, monitor site improvements, and/or gain a greater understanding of the dynamics of the client-service provider interaction (Boyce et al., 2006; Wilson, 2001). Previous mystery client studies dedicated to reproductive health issues and services informed the design of this study (Chin-Quee et al., 2006; León et al., 2005; Huntington et al., 1993).

Data collection procedures

I employed purposive sampling techniques to identify 122 retail pharmacies in three cities in different regions of the country: São José dos Campos (site 1), Fortaleza (site 2), and Brasilia (site 3). I visited 42 pharmacies in site 1, 41 in site 2 and 39 in site 3, with specific attention to the neighborhood and catchment area and devoted three weeks of research in each city.

The three cities were purposively selected because of their geographic, socioeconomic, and cultural diversity. Fortaleza is the capital of Ceara (CE), located in northeastern Brazil. This region is characterized by a lower socioeconomic level than the rest of the country. Brasilia is the capital

located in the Federal District (DF) in the mid-west region of the country. Brasilia offers a high quality of life index and high per capita income (IBGE, 2014). However, the capital also reflects tremendous inequality, hosting one of the largest slums in Latin America. Finally, I selected São Jose dos Campos, located in the state of São Paulo, in the southeast region of the country. Although the quality of life index is relatively high, this is the most industrial region of the country. These study sites are marked on the map included in Appendix A.

The sample size follows the recommendations of the optimal sample size for qualitative research as explained by Marshall, Cardon, Poddara and Fontenot (2013). According to their study, rigor in the sample size determination and in the selection of the sample participants is vital in qualitative research. They argue that rigorous qualitative research should include between 20 and 30 interviews.

The priority for inclusion as a participant in the research reflected a randomized geographic location within each city, taking into account location, opening hours, more busy or less busy times, presence or absence of the pharmacist, and logistical and safety/security issues. Upon the selection of the sample for the research, which included 11 different neighborhoods, a schedule for the visits was developed and then followed as accurately as possible. However, rescheduling occurred in all three sites. In Sao Jose dos Campos, some pharmacies were closed on Sundays, in discordance with the posted hours. In Fortaleza, a large chain of pharmacies had to be excluded after the confirmation that it did not carry any kind of emergency contraceptives. In Brasilia, some rescheduling accommodated the visits to libraries and archives.

In qualitative inquiries, the researcher is the instrument in the study (Creswell, 2013). In other words, he or she plays a major role in terms of data collection (Creswell, 2013). In this study, I was the researcher involved in the mystery client component, collecting primary data from the

pharmacists. According to Creswell (2013), a researcher's role is to collect data through participants. In most cases, these are tools such as interviews, surveys, or questionnaires, in this case, the Mystery Client Profile, which is in Appendix C.

This design is observational because I approached each pharmacy as if I was a client in search of emergency contraception and I began each interaction with "I hear there is something that you can give me to prevent pregnancy after sex." I then allowed the interaction to unfold organically.

Based on a predetermined client profile shown in Appendix C, I responded to questions asked by the pharmacist/pharmacy technician. I enquired about efficacy, side effects, and the number of times in a year one can take the medication (if the pharmacist did not offer this information). These interactions occurred in Portuguese with "natural" language to mimic a real clinician-patient interaction and concluded with either the decision not to purchase the medication or, if EC was not available, a request for referral. Each interaction took five minutes, on average and focused on levonorgestrel ECPs.

Immediately after the interaction, and in the absence of the pharmacist/pharmacy technician, I took notes to capture detailed information about the interaction. I included in these notes information about availability (stock, brand, price) as well as the information requested and the information provided (and the medical accuracy of that information). I performed an assessment about the tone of the interaction and other impressions; all this information formed a database created specifically for this project. After each day of collecting data, I engaged in a formal memoing process to reflect on these experiences, explore my reactions, and facilitate the interpretation process. There was no reason for me to collect personally identifying information

about the pharmacist/pharmacy technician (Denscombe, 2012) and I did not record the names of pharmacies or health service providers.

Data analysis and interpretation

The basic findings (stock, price, content, medical accuracy) were analyzed using descriptive statistics in Microsoft Excel®. The interactions for content and themes were analyzed using both deductive and inductive techniques. According to Braun and Clarke (2006), thematic analysis involves identification, analysis, and reporting of major patterns and themes found in data collected. This approach respected the following steps:

- i. Reading notes to determine the meaning of words
- ii. Clustering collected data into content and themes
- iii. Examining the relationships between themes and related literature

In addition, in the final phase of this project, I examined the findings from the two components in relationship to each other. This process allowed me to reflect on the ways in which the journey of EC impact current availability as well as identify possible avenues and strategies for improving access.

2.5 Ethical considerations

The first component of this project involved the collection of existing materials and thus no human research participants were involved. Because the second component of the study evaluated professional provision practices and did not involve collecting personally identifying information about individuals, my supervisor consulted the Director of the Office of Research Ethics and Integrity at the University of Ottawa; the Director confirmed that Research Ethics Board approval was not required for this research project. For all future publications, I have permission

to use the following statement: “Based on the criteria laid forth in Article 2.1 of the Tri-Council Policy Statement, 2nd Edition, the Office of Research Ethics and Integrity at the University of Ottawa determined that this study does not involve “human participants” and therefore did not require Research Ethics Board review.”

Chapter 3: Results of Component 1

The journey of emergency contraception in Brazil reflects evolving policies, politics, and priorities by both the government and individuals and is tied to broader cultural perceptions on sexual and reproductive health and rights. The history of EC showcases the role of the Brazilian feminist movement and other social forces that influence providers' and potential users' perceptions and the myths about the medication that circulate.

3.1 The journey of EC in Brazil's health care system

According to Vieira (2003), during the 1960s and 1970s, family planning was controversial because there was clear disagreement between the Catholic Church, intellectuals and scholars, and groups that formed the military government. Costa et al. (2006) argues that the Brazilian government acted ambiguously, taking a cautious stance with respect to fertility control and family planning policies but being permissive with respect to private entities. This opened a window for foreign, non-governmental organizations (NGOs) to play a significant, albeit is uncoordinated, part in the provision of family planning services. Beginning in 1965, international-agency sponsored family planning clinics proliferated and contraceptive sales increase (Vieira, 2003). During this early phase the promotion of contraceptive and the emerging policies focused on population control and demographic goals. The Civil Society of Family Welfare in Brazil (BEMFAM) and the Center for Research on Integrated Assistance to Women and Children (CPAIMEC) were the most relevant examples.

A major shift occurred in the 1980s, a period marked by the radicalization of the military's discourse regarding demographic control (Costa et al., 2006; Vieira, 2003). This radicalization triggered outrage from new social actors, among them the emerging feminist movement. The

feminist movement criticized the government's targets for family planning, believing that these efforts aimed to increase the use of contraceptives to achieve demographic goals, not to safeguard women's rights. Influenced by global feminist discourse, the Brazilian feminist movement began to articulate the importance of having control over one's own body and advancing reproductive rights. In calling for women's reproductive autonomy, the feminist movement also challenged the authoritarian government more broadly (Ávila and Corrêa, 1999; Vieira, 2003).

It is within this backdrop that EC first reaches Brazil in the mid-1990s (Paiva, 2014). The first reference to EC in national policy guidelines occurred in the 1996 Family Planning Act. According to Hardy and colleagues (2001), the relatively positive legal and political climate allowed for incorporation of EC into the Ministry's Family Planning Manual. However, initially EC was available only to survivors of sexual violence; Brazil's efforts to combat violence against women in the 1990s were widely hailed as trailblazing and thus incorporation of EC into sexual violence response was consistent with these efforts (Souza & Brandão, 2009). Chapter 1 of the 1996 policy referenced the use of the Yuzpe method as a treatment for sexual assault patients (Paiva, 2014; Galvao et al., 1999; Santos et al. 2014; Alano, Costa, Miranda and Galato, 2012; Hardy et al., 2001). According to Figueiredo (2004), public health services in Brazil did not initially comply with these norms, causing a gap in service availability. However, a 2005 study by Oshikata, Bedone and Faúndes indicated that 76% of sexual violence survivors treated through SUS received ECPs as part of their post-rape care.

However, broader incorporation of EC into reproductive health proved challenging because some politicians considered it as a way of "legitimizing abortion" (Hardy et al., 2001; Figueiredo and Peña, 2002; Figueiredo, 2004). In 1998 issues its first technical note on EC, which stated clearly that EC is not an abortifacient. In 1999 ANVISA approved the first levonorgestrel

ECP (Postinor2®); the medication required a prescription but could be sold through retail pharmacies. But it wasn't until the mid-2000s that concentrated efforts increased the availability of ECPs to all women; in 2005, the Brazilian Ministry of Health increased the distribution of EC in the public sector by 57%, with the intention of providing it to all women, not only to victims of sexual violence (Paiva, 2014; Díaz, Hardy, Alvarado, Ezcurra, 2003; Souza & Brandão, 2009). According to Suwwan (2005), this measure was part of the new Brazilian sexual and reproductive rights policy which mandated the distribution of ECPs to all women and promoted independent family planning. However, logistical challenges continued to plague the public health system and thus actual availability of progestin-only ECPs in public pharmacies, health centers, and hospitals varied widely and depended more on the logistic capacity of the local government than on the strength of the local public policy (Faúndes et al., 2007).

In 2005, the Ministry of Health started an information campaign with the publication of “Emergency Contraception: Questions and answers for health professionals” (Brazil, Ministry of Health, 2005). Using the question and answer format the Ministry of Health hoped to help health professionals integrate EC into their practices and better respond to individual women’s comprehensive reproductive health needs (Costa, Ferraz, Souza, Silva & Almeida, 2008). The manual was updated in 2011. The Ministry of Health also updated the technical note in both 2005 and 2006 (Brazil, Ministry of Health, 2006). The most recent version presents the definition, mechanism of action, indications of use, and other clarifications about progestin-only EC. Importantly, the technical note correctly states that the window of time to start treatment is up to 5 days after unprotected intercourse and that the medication will not cause an abortion. Since 2006, there have been no major changes in EC-related policies. Although debates about the availability

and accessibility of EC continue (Souza & Brandão, 2012), ANVISA's public database indicates that 11 brands of progestin-only ECPs are currently available in Brazil.

The policy trajectory of EC in Brazil was also influenced by international stakeholders, particularly the International Consortium of Emergency Contraception (ICEC). Faúndes et al. (2007) argue that the advocacy by the ICEC raised awareness about EC among decision-makers and health service providers throughout Latin America, and especially Peru, Brazil, and Chile. Among the actions of ICEC, Martin (2004) highlights the Regional Conference on the Right to Emergency Contraception in Latin America. Held in Ecuador in 2002, representatives from 20 countries participated. The main objectives of this conference were to increase knowledge and acceptance of EC as a safe and effective method and to call on policy makers to support the inclusion of the method in the official standards of family planning in Latin countries. Prior to this conference, only 10 countries had incorporated EC into their norms and guidelines and only 13 countries had registered a dedicated product. By 2004, 18 countries had officially adopted EC-related policies and 19 countries had registered at least one emergency contraceptive products. The overarching regional provided support for the actions of the Brazilian Ministry of Health in the mid-2000s.

3.2 The journey of EC in Brazilian society

Over the last 20 years, emergency contraception has dramatically gained acceptance and visibility, particularly among the women, in Brazil (Souza & Brandão, 2009). However, evidence suggests that both knowledge and general use of emergency contraception (that is, use outside of the context of sexual assault) is low. According to the National Data on Women's and Children's Health and Demographics in 2006, 12% of the women between 15 and 49 years of age had used

ECPs at least once (Brazil, Ministry of Health, 2009). Progestin-only EC stands as the fifth most widely used contraceptive method in the country (Paiva, 2014). Even though it is evident that the drug is safe and effective, it remains underused (Heimbürger, Gras & Guedes, 2003). The influence of the Catholic Church on both individual and the collective perceptions of EC and social taboos regarding teen sex and pregnancy appear to be shaping these dynamics.

As is the case of much of Latin America, the Catholic Church plays a significant political and cultural role in Brazil (Faúndes et al., 2007). Conservative political influences are often intertwined with religious beliefs and these attitudes have created policy, rhetorical, and cultural barriers to the widespread use of EC. Conservative stakeholders publicly criticized the 2005 National Policy on Sexual Rights and Reproductive Rights (Souza, 2008) and encouraged to Municipal Councils to adopt alternative policies. As a result, in 2005 the São José dos Campos Municipal Council banned the distribution of the EC received by the Ministry of Health and in 2008 the Jundiaí City Council prohibited the use of EC in the municipality's public health centers. Those laws persisted until 2006 and 2009, respectively, until they succumbed to legal actions.

However, beyond policies, the positioning of the Catholic Church has created misinformation about emergency contraception. Ignoring all scientific evidence on EC's mechanism of action, the Catholic Church maintains that progestin-only EC causes an abortion. Catholic stakeholders have actively disseminated misinformation about the drug's mechanism of action through websites, brochures, magazines, and other publications. Moreover, in Brazil some priests have become celebrities with powerful influence. They have been using both the conventional media and social media to spread misinformation about EC to the public, particularly targeting young adults and teenagers. Given overarching discomfort with public discussion about adolescent sexuality, this misinformation may go unchallenged (Schalet, 2004).

Yet pregnancy among adolescents is a significant public health issue in Brazil. Approximately 23% of registered live births are to women between the ages of 15 and 19 (Figueiredo, 2004). Data from the Ministry of Health indicate that the fertility rate among adolescents has increased by 26% since the 1990s; during this same period the fertility rate among adult women has decreased. In general, teenage pregnancy, particularly among younger girls, is riskier than adult pregnancy. Although some argue that pregnancy among adolescents is reflective of a latent desire to become a mother, most health institutions and researchers recognize that the high rates of teen pregnancy reflect compounding social vulnerabilities (Brazil, Ministry of Health, 2007). As a result, the Brazilian Ministry of Health has unequivocally stated that it is necessary to guarantee the reproductive rights of adolescents and young adults, including access to EC (Brazil, Ministry of Health, 2007). Further, Diaz et al. (2003), Pinto Costa et al. (2008), Martin (2004), and Faúndes et al. (2007) indicate that in Latin America there are two main reproductive health problems: unplanned pregnancy leading to unsafe abortion and teenage pregnancy. Indeed, in Brazil about 25% of unplanned pregnancies result in an unsafe and/or clandestine abortion (Saito and Leal, 2007). In this context EC could play a significant role.

However, a vocal minority of health professionals have constantly expressed concern about use of ECPs by adolescents. These objections tap into broader societal concerns that access to EC will result in adolescents' abandonment of ongoing contraception methods (Berer, 2006). However, scientific evidence does not support this position. As an example, Figueiredo and Andalaft (2005), who investigated women and teenagers from 15 to 24 years, found that access to and information about emergency contraception did not result in discarding other contraception methods, such as condoms or oral contraceptives.

That some health service professionals are opposed to EC, especially among adolescents, is unsurprising given empirical research that suggests providing practices vary widely and are non-transparent, despite clear guidelines from the Ministry of Health and the Federal Council of Physicians (Hardy et al., 2001; Osis et al., 2006). Hardy et al. (2001) and Diaz et al. (2003a) argue that the dissemination of information about EC must target the health services, where myths and misinformation are rampant. Of course misinformation among health professionals is often communicated to patients, and thus a number of researchers have called for information campaigns to address issues related to safety, mechanism of action, and impact of use on other behaviors (Díaz et al., 2003a ; Díaz et al., 2003b ; Martin, 2004 ; Faúndes et al., 2007). Further, as women are now able to obtain progestin-only ECPs from retail pharmacists, it is important to also target women directly (Araújo & Costa 2009; Hardy et al., 2001, Diaz et al., 2003a)

EC is currently available throughout retail pharmacies in Brazil and thus women do not need to engage with the public sector to obtain the medication. This “ease of access” has engendered some debate and contributes to overarching misinformation (Figueiredo, 2004). Given the availability of progestin-only EC, Pinto Costa and colleagues (2008) argue that misinformation and moral and cultural dynamics significantly shape access.

However, access to ECPs in Brazil is uneven mainly because of women’s diverse financial and cultural realities. In retail pharmacies, emergency contraception should require a prescription for purchase, but this requirement, regulated by ANVISA, is not respected. The cost of emergency contraceptive pills is around US\$ 2–7 per dose, an amount that is out of reach for most women, especial poor women and adolescent girls (Ferreira, Souza, Lima & Braga, 2010). According to Alano et al. (2012), in the public network of community health centers, where access to ECPs is free of charge, availability of ECPs is often minimal or non-existent due to conservative beliefs,

logistical constraints, and misinformation about policy makers and providers. In addition, women's lack of awareness of their own bodies and of sexual and reproductive health issues more generally, and fear of side effects and the consequences of prolonged use, impacts knowledge of an demand for the medication (Alano et al. 2012; Hardy et al., 2001; Diaz et al., 2003).

However, there is also some evidence of growing support for EC, particularly among women. Consistent with the increased visibility of the Brazilian feminist movement and the discourses employed, there is growing acceptance of the belief that women have a right to sexual and reproductive health services, including EC. Further, in recent years, EC has been framed as a solution that can alleviate the burdens associated with adolescent pregnancy, unwanted pregnancies, and unsafe abortions.

In conclusion, the textual and discourse analysis reveals that a complex combination of factor influences the use of ECPs in Brazilian society. The evolution of the Brazilian public policy showed that, as important as passing laws and publishing guides are, it is essential to invest in providing correct information to the public regarding safety, mechanism of action, and correct use. Raising awareness among health services providers and the public will continue to be critical for EC to become fully integrated within sexual and reproductive health services for all women in Brazil.

Chapter 4: Results of Component 2

We published the findings of the mystery client study in *Contraception*. In this chapter I provide a copy of the pre-publication version of the manuscript; the full citation for the published article is: Tavares, M., Foster, A. M. (2016). Emergency contraception in a public health emergency: Exploring pharmacy availability in Brazil. *Contraception*, 94, 109-114.

Emergency contraception in a public health emergency: exploring pharmacy availability in Brazil

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Abstract

Introduction: Dedicated progestin-only emergency contraceptive pills (ECPs) have been available with a prescription in Brazil since 1999. However, utilization of emergency contraception has been limited. We conducted a mystery client study at retail pharmacies in three regions to assess current availability.

Methods: Using a predetermined client profile, we approached a random sample of chain and independent pharmacies in urban areas in the southeastern, northeastern and central-west regions. We documented product availability, price and the client-pharmacy representative interaction at each site. We analyzed these data with descriptive statistics and for content and themes.

Results: We visited 122 pharmacies in early 2016. All but three pharmacies (97.5%) had ECPs in stock at the time of the interaction and offered our client the medication without a prescription. In general, pharmacy representatives did not ask questions or provide our client with information about emergency contraception. When prompted, over one third of the pharmacy representatives (37.7%) inaccurately reported that levonorgestrel ECPs could only be used immediately or within 12, 24 or 48 h from the time of intercourse.

Conclusion: Despite the current regulatory status, our findings suggest that progestin-only ECPs are widely available without a prescription. Additional efforts to ensure that women have up-to-date and medically accurate information about progestin-only ECPs appear warranted. Our findings suggest that more work needs to be done to align national regulatory policies with international standards and evidence-based practices.

Keywords: EC; ECPs; Postcoital contraception; Zika virus; Latin America

Implications: The Zika virus epidemic has shined a spotlight on the importance of providing timely access to emergency contraception in Latin America. This public health emergency offers a window of opportunity to advance national policies and practices to ensure that Brazilian women have access to a full range of reproductive health services.

1. Introduction

Emergency contraceptives are medications or devices used postcoitally to reduce the risk of pregnancy. Globally, the most common modality of emergency contraception (EC) is the progestin-only pill, which is currently registered in nearly 150 countries and on dozens of national Essential Medicines Lists [1]. The safety of progestin-only EC has been well established [2] and, as of early 2016, dedicated levonorgestrel (LNG) emergency contraceptive pills (ECPs) were available directly from pharmacies in 80 countries worldwide [1].

EC was first incorporated into the Brazilian national family planning program and into sexual assault treatment guidelines in the mid-1990s when reference was made to postcoital use of combined hormonal pills [3,4]. In 1999, the Agencia Nacional de Vigilância Sanitária approved the first dedicated LNG-EC product, Postinor-2®, for prescription sale [5]. ECPs became incorporated into the Brazilian public health system as well as through the retail pharmacy sector [3]. By the end of 2015, there were more than a dozen one-pill and two-pill LNG-EC products registered [1].

Ensuring that women have timely and affordable access to a full range of contraceptive methods, including postcoital contraception, has long been a priority in the international reproductive health and rights community [6]. Brazil enjoys a robust contraceptive method mix but coverage through the national health system (the Unified Health System, SUS) varies. Sterilization procedures are covered by SUS in secondary-level health facilities after assessment and referral. The Copper-T intrauterine device (IUD), oral contraceptive pills (OCPs), diaphragms and condoms are covered by SUS and available free of charge from primary care facilities; OCPs technically require a prescription but are available directly from pharmacies [7,8]. In contrast, combined hormonal rings and patches, contraceptive implants and the

progestin-releasing IUD are not covered by SUS but are available [8]. In early 2016, the Brazilian government announced that it would begin studying the possibility of offering SUS coverage for the latter two methods [9]. In Brazil, abortion is only legally permissible when the pregnancy threatens the life of the woman, is the result of rape or includes a diagnosis of an anencephalic fetus [7]. Unsafe abortion is a significant public health problem and major contributor to maternal morbidity in the country [10]. Given this overarching context, EC has the potential to play a critical role in facilitating an individual woman's ability to prevent unwanted pregnancy.

However, utilization of LNG-EC has been limited. Several factors have likely influenced this dynamic, including misinformation and/or lack of awareness among both clinicians and potential users, the inconsistent availability of ECPs through the public sector and the price of the medication in retail pharmacies [3,11–14]. That Brazil also officially continues to require a prescription for all progestin-only EC products may also be an impediment to timely access. Despite this regulatory requirement, several studies have indicated that Brazilian women obtain ECPs directly from pharmacies [3,13]. However, to date, no research has documented the availability of EC in or the service delivery practices taking place at pharmacies. In 2016, we conducted a mystery client study in three Brazilian cities to shed light on EC availability and provision in retail pharmacies.

2. Methods

Our study design was informed by previous mystery client studies conducted in other settings [15–18]. Over a 6-week period in January and February 2016, we conducted in-person visits at retail pharmacies in three locations, purposively chosen for their geographic and socioeconomic diversity. São José dos Campos (Site 1) is located in the southeastern state of Sao

Paulo and, in 2011, had an average per capita gross domestic product (GDP) of US\$19,386 [19], significantly above the national average of US\$13,042 [20]. Fortaleza (Site 2) is the capital of the northeastern state of Ceará with a below average per capita GDP of US\$6162 [19]. Brasília (Site 3) is the national capital and constructed urban center located in the center-west region. At over US\$37,000 [19], the per capita GDP in Distrito Federal was the highest in the country in 2011, but Brasília is also home to growing slum settlements, reflecting tremendous income inequality. Our study sites are depicted in Fig. 1.

2.1. Data collection

We aimed to visit 40 pharmacies in each study site, including both chain and independent pharmacies in different neighborhoods. We used a stratified random selection process to identify sites for inclusion. MT, a Brazilian national completing her MSc degree in Interdisciplinary Health Sciences at the University of Ottawa (Canada), conducted all visits. Traveling by bus, car or on foot, she presented herself at the pharmacy and either approached or asked to speak with a pharmacist. She then initiated each interaction (in Portuguese) with “Do you have the day after pill?” Using a predetermined client profile to respond to questions (Fig. 2), MT then let the interaction unfold organically, with a prompt, if necessary, of “I have never used this medication. How do I use it?”

Interactions averaged 5–10 min in length. Immediately after each interaction and after leaving the pharmacy, MT field coded and took detailed notes about the interaction. At the end of each day, MT engaged in a formal memoing process to reflect on the dynamics of each encounter and initiate the analytic process.

2.2. Data analysis

We entered field coded data into Microsoft Excel® and analyzed the results using descriptive statistics. We analyzed the field notes and memos for content and themes using both deductive and inductive analytic techniques [21]. Regular meetings between MT and her supervisor (AF) guided our interpretation and we resolved differences through discussion.

2.3. Ethical considerations

Based on the criteria in Article 2.1 of the Tri-Council Policy Statement, 2nd Edition [22], the Office of Research Ethics and Integrity at the University of Ottawa determined that this study did not involve “human participants” and therefore did not require Research Ethics Board review. In this article, we have masked all identifiable information about individual pharmacies and their personnel.

3. Results

3.1. Pharmacy and encounter characteristics

We visited 122 pharmacies in 11 distinct neighborhoods in São José dos Campos (n=42), Fortaleza (n=41) and Brasília (n=39). Consistent with the retail pharmacy sector in Brazil overall and in our study regions [23], over three quarters of our sample (n=94, 77.0%) were chain pharmacies and the remainder were independent. Just shy of 80% (n=97) of our interactions were with pharmacists; in the remaining 25 pharmacies, a pharmacist was unavailable and thus our encounter took place with a pharmacy technician or sales clerk. However, we were more likely to encounter a pharmacist in São José dos Campos (n=40, 95%) than in Fortaleza (n=27, 66%) or Brasília (n=30, 77%).

3.2. Availability of ECPs

Representatives from almost all the pharmacies included in the study (n=119, 97.5%) reported that the pharmacy carried at least one brand of LNG-EC. One independent pharmacy in

São José dos Campos and two pharmacies from the same regional chain in Fortaleza did not stock the drug; both pharmacists affiliated with the chain reported that LNG-EC was not available as a matter of chain policy. Pharmacies in our sample carried seven different branded and generic EC products, including both one-pill and two-pill formulations, and the average price was US\$2.32 (range: US\$1.25 to US\$5.75). Although progestin-only EC remains prescription-only, none of the pharmacy representatives in our sample asked for a prescription or required a prescription for purchase.

3.3. (Mis)information provided about EC

None of the pharmacy representatives in our study asked our mystery client any questions or offered to provide her with information about the medication. However, after prompting, our client was informed in over a third of the encounters (n=46, 37.7%) that the window of eligibility was less than 72 h. This includes pharmacists and pharmacy representatives who explained that EC had to be taken “immediately” or within 12, 24 or 48 h. As one pharmacist explained, “You must take it [within a] day of the intercourse, that is why it is called the next day pill!” Twenty pharmacy representatives (16.4%), including all three of those who worked at locations that did not stock EC, provided either no information or vague information about when EC could be used. The misinformation and/or lack of information about the timeframe for use occurred among all types of pharmacy representatives, at all three sites and in both chain and independent stores. Consistent with the product labels, pharmacy representatives in nearly half of our interactions (n=56, 45.9%) explained that LNG-ECPs could be used up to 72 h after unprotected intercourse.

Overall, representatives from the pharmacies in our study demonstrated accurate knowledge of the side effect profile of LNG-ECPs. Most of the pharmacists, pharmacy

technicians and sales clerks referenced the medication's minimal side effects. As exemplified by one pharmacist from Fortaleza, “[Side effects] may include nausea or cramps, but these are rare, and you don't have to worry about them.” A sizeable minority of our respondents overall (n=31, 25.4%) and of our nonpharmacists in particular (n=9, 36%) were completely dismissive of side effects. Several pharmacists also warned our client about delayed or disrupted menstrual periods. Four pharmacy representatives (3.3%) inaccurately reported that the side effects of LNG-EC were the same as combined hormonal OCPs. Notably, none of the pharmacy representatives who offered a two-pill brand recommended that our mystery client take both pills at once and no one provided her with information about when to follow-up with a pregnancy test/clinician (in the case of a suspected pregnancy) or when different types of ongoing methods could be initiated.

4. Discussion

The availability and accessibility of ECPs in Brazil has taken on new urgency with the recent Zika virus (ZIKV) outbreak. Autochthonous transmission of ZIKV was first confirmed in Latin America (Easter Island, Chile) in 2014 and then in Brazil in April 2015 [24]. As reported by Paixao et al., estimates from the Brazilian Ministry of Health suggest that as many as 1.3 million people were infected with ZIKV in 2015, with the highest documented infection rate in the northeast region of the country [24]. Beginning in October 2015, public health authorities in several northeastern states reported significant increases in the number of cases of microcephaly [25]. A causal relationship between ZIKV infection and microcephaly is strongly suspected and, in February 2016, the World Health Organization (WHO) declared the situation a “Public Health Emergency of International Concern” [26]. Although a multifaceted, multisectoral response to ZIKV is underway, the WHO has also specifically called for women who have had unprotected

sex and are concerned about ZIKV exposure to have “ready access to emergency contraceptive services and counseling” [27].

Our findings regarding the availability of LNG-EC in Brazil are encouraging. Despite the technical requirement for a prescription, we found that ECPs were widely available directly from both chain and independent pharmacies at consistent prices in three very different regions. Given the clear safety of the product, embarking on a formal regulatory shift to nonprescription status could help ensure continued pharmacy access.

However, our findings also suggest that a northeast regional pharmacy chain does not stock LNG-ECPs. Given that the northeast region has been most impacted by ZIKV [25] and this particular pharmacy chain is one of the most dominant in the region, this result is concerning. Progestin-only ECPs are included on the Brazilian Essential Medicines List [1], which is an indication of their importance, and thus, this may be the time to engage in a more public discussion about the responsibility of pharmacies to carry essential products.

That our mystery client was not subjected to intrusive questioning or asked to justify her need for LNG-EC is heartening. Indeed, our client never had to reveal any of the information that we developed for her profile. However, when asked, a sizeable minority of pharmacy representatives provided an overly narrow timeframe for use that could dissuade eligible women from taking LNG-EC. Although efficacy is greatest if the medication is used as close to the sexual event as possible, 1.5 mg of LNG can be used up to 120 h after unprotected or underprotected sexual intercourse [2,28]. Circulating information to pharmacists with information about the evidence-based timeframe and the advantages of taking the full dose at one time and redoubling efforts to inform women about LNG-EC's availability and indications for

use appear warranted. Identifying avenues for increasing access to more effective methods of EC, such as the postcoital insertion of the Copper-T IUD, may also address a significant need.

However, efforts to increase access to EC will not address the needs of those women who become pregnant and lack access to safe and legal abortion care. The ZIKV crisis has shined a spotlight on the legal status of abortion in much of Latin America, including Brazil. This international public health emergency may offer a window of opportunity for activists, clinicians and public health specialists to mobilize for evidence-based contraception and abortion policies that offer all women, not just those who have been exposed to ZIKV, greater reproductive autonomy.

5. Limitations

Although our study offers a picture of ECP availability in Brazil, we restricted our mystery client visits to urban areas in three regions. Thus, we are unable to comment on availability in other regions of the country or in rural areas. Research on LNG-EC availability in the state of Paraíba, the area with the largest number of confirmed and suspected microcephaly cases [29], could be especially valuable. Further, although retail pharmacies are important, future research would benefit from exploring EC availability at other service delivery points, including public sector facilities, and from a range of providers. Finally, the nature of a mystery client study is that the researcher embodies the client profile. In posing as a university educated, unmarried woman in her 20s, we were able to explore EC availability for women of this demographic. Pharmacy representatives may interact with women from other groups, including teens and younger adolescents, differently.

6. Conclusion

Our mystery client study in three Brazilian cities suggests that LNG-ECPs are widely available without a prescription. Additional efforts to ensure that women have up-to-date and medically accurate information about LNG-ECPs appear warranted. The public health emergency created by the Zika virus outbreak may offer a window of opportunity to work toward further aligning reproductive health regulations and policies with international standards and evidence-based practices.



Fig. 1. Map of Brazil with microcephaly cases (as of January 2016) and study sites indicated [29].

Mystery client profile

Maria is a 26-year-old woman who is visiting her fiancé (location altered per study site). She and her partner typically use condoms but did not do so when they had sex the night before.

Although she has never used emergency contraception, when she was in university she had friends who talked about “a pill” that was taken after sex to prevent pregnancy. She has no health problems or allergies and takes no medications on a regular basis. Her last period ended about a week earlier.

Fig. 2. Mystery client profile.

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Chapter 5: Discussion

5.1 Integration of results

This study focused on an analysis of the history of government policies and past and current societal perceptions of emergency contraception to understand the factors and dynamics that shaped EC;s incorporation into the Brazilian health system. Additionally, our field-based research sought to assess the availability of progestin-only ECPs in retail pharmacies in three Brazilian and understand real world practices. The integration of these results provides insight into the avenues that might be explored to improve the availability and accessibility of ECPs in Brazil.

The findings of the mystery client study suggest clearly that despite the current regulatory requirement for medical prescriptions, progestin-only ECPs are widely available without a prescription from retail pharmacies. However, the medication rests behind the counter, and therefore “hidden,” forcing the potential user to approach the pharmacy staff and ask for it. No visited pharmacies, chain or independent, had the medication in sight. Given the social taboos that continue to surround EC, and the broader social taboos surrounding adolescent sex and pregnancy, the “behind-the-counter” (BTC) status could pose a barrier to access. Changing the regulatory status of progestin-only ECPs so that they could be provided over-the-counter (OTC) could improve access. Although this would require a long review process by ANVISA, this would also align with the current status of ECPs with more than 60 countries worldwide (ICEC, 2016).

However, researchers have also argued that, apart from pregnancy prevention, emergency contraceptives can serve as a link to the health care system and help women bridge to ongoing contraceptive methods (Sunil & Hoblidar, 2016). Provision of EC also had great potential to prompt conversations on issues related to sexual and reproductive health more broadly. However, our results suggest that current service delivery in retail pharmacies reflects the worst of both

worlds; women do not have OTC access to the medication but pharmacists are not providing women with evidence-based and accurate information during their encounters and are not discussing ongoing contraceptive methods.

The findings of this study strongly suggest that additional efforts are essential to ensure that women have up-to-date and medically accurate information about progestin-only ECPs. And the results from both components of the project indicate that the priority target population for awareness raising campaigns is health professionals. Indeed, the mystery client study showed that some staff at retail pharmacies mistakenly believe that ECPs are effective only within a few hours of, or only in the day following, sexual intercourse. The discourse analysis revealed that physicians and public pharmacy technicians play an important role in the spread of misinformation about ECPs. Further, some health professionals are hesitant to offer ECPs because they have entrenched cultural perceptions associating emergency contraception to abortion (Souza & Brandão, 2012). Health professionals need to have a comprehensive understanding of progestin-only ECPs, including the protocol for use, side effects, and mechanism of action

Sunil and Hoblidar (2016) investigated EC knowledge, attitudes, and practices among gynecologists; 72% of their participants were women. Approximately 84% reported that they did not routinely provide clients with information about or offer progestin-only ECPs. However, all of the study participants were aware that levonorgestrel EC is a form of post-coital contraception. Further, misinformation about progestin-only EC abounded; only 64% of respondents were able to correctly cite the dosage and protocol for use. Roughly 12% of the participant gynecologists reported that progestin-only EC is a form of abortion and 58% of the respondents believed that EC promotes irresponsible and promiscuous behaviors. Finally, 60% felt that targeting progestin-only ECPs at unmarried adolescents may undermine parental authority and community morals. The

results of this study provide a stark reminder of the important role that health service providers play in shaping the way a reproductive health technology is framed and whether or not it is offered. The findings from this study confirm that there is an urgent need to create greater awareness among all health professionals about EC.

The textual and discourse analysis indicate that conservative values and Catholic positions on emergency contraception have shaped the beliefs of health care providers and the general public and have impeded public sector availability. The absence of large-scale proactive efforts to counteract these views through the spread of evidence-based information by reliable government and professional society sources has led to persistent confusion about the mechanism of action. That one retail pharmacy chain in our study refuses to stock progestin-only ECPs as a matter of policies suggests that these conservative and religious values may be influencing some in the private sector as well.

Studies with university students (Silva et al, 2010) and adolescents (Araujo and Costa, 2009) in Brazil have shown that EC has begun to seep into the public consciousness; in both students nearly all participants had heard of EC. However, knowledge of how and when to use the medication was minimal. These studies also found rural-urban and regional disparities in knowledge and that there continues to be a persistent belief that EC induces an abortion and/or causes significant health risks. These studies echo our findings that suggest national level awareness and educational campaigns are warranted.

However, there are a multitude of challenges to launching these efforts. Indeed, findings from this thesis suggest that Brazil has been struggling to deliver accurate information about EC and reproductive health more generally for decades. Conservative and religious stakeholders have thwarted efforts to develop comprehensive and up-to-date sexual and reproductive health

education programs in public schools and social taboos around adolescent sexuality often inhibit discussions within the community or the family. Identifying ways to integrate medically accurate information about EC into education programs would be an important step to advancing national policies related to sexual and reproductive health and rights. Taking advantage of the explosion of social media and targeting messages at teens and adolescents using lay language and innovative approaches could improve awareness.

But these efforts will be for naught if health service providers do not offer the medication or if available product is unaffordable. The outbreak of the Zika virus and the public health emergency created by the epidemic shined a spotlight on Brazil's sexual and reproductive health policies. Renewed pressure was placed on the government to align policies with global standards and push back on the misinformation espoused by the Catholic Church. This may prove an important window of opportunity for the public sector to play a more significant role in EC service delivery.

5.2 Future Directions

I intend on sharing the findings from this study with various stakeholders in Brazil and Canada. I will also continue to present the findings from my study academic meetings in both Canada and Brazil. This study can serve as a base for other scholars working on EC in Brazil, in particular, and Latin America, in general.

Many of the existing investigations on EC in Brazil have paid a great deal of attention to legal and regulatory issues and the barriers to access. However, in compiling information through this project it is clear that significant challenges exist in public health provision. Exploring avenues to approve affordable and timely access through the public sector appears warranted (Souza &

Brandão; 2009; 2012). Renewed discussions about the regulatory status of progestin-only ECPs, including a shift to OTC availability, could address major access barriers. The Zika-related microcephaly outbreak highlighted the need to align reproductive health policies with global norms and standards.

Finally, the approval of UPA may provide a window of opportunity to improve access to all modalities of EC. Even though progestin-only ECPs are safe they are less effective than both UPA and the copper-T IUD. Launching efforts to improve access to a full range of EC methods could meet a critical women's health need in Brazil.

5.3 Limitations of the Study

This study has a number of limitations. Regarding the discourse analysis component, the amount and quality of available literature was less than ideal, and the time constraints to perform visits to local archives and libraries forced me to rely heavily on online sources. Additionally, this study did not focus in other EC methods, such as the copper-T IUD or ulipristal acetate. I found little information about these methods in published works and the approval of UPA (December 2015) occurred only a few months before my fieldwork. Future work would benefit from exploring a full range of EC modalities.

This study also faced important limitations with respect to the mystery client study component. For example, although qualitative research does not aim to be representative or generalizable, Brazil is a very populous and diverse country. For financial, logistical, temporal, and safety reasons, I focused retails pharmacies in three cities and in accessible neighborhoods within those cities. Although these areas are diverse, I was not able to capture a full range of regional and neighborhood dynamics. Further, for practical reasons I limited my study to

urban/suburban areas; future research could investigate the availability of progestin-only ECPs in rural areas. Finally, we acknowledge that the availability of ECPs in public pharmacies is likely drastically different from the availability of ECPs in the retail sector and may vary even more widely by geographic location.

5.4 Positionality and Reflexivity

Positionality and reflexivity are critical issues in qualitative research. Positionality centers on the influences that the researcher's identity and experiences have on his/her collection and interpretation of the data (Rose, 1997). Reflexivity is an active process where the researcher acknowledges and explores the interplay between his/her own personal experience and identity on the research process and the study's conclusion (Dowling, 2006).

As a woman that was born and raised in Brazil, I am aware of the cultural, social, and economic factors that shape the development of reproductive health in the country. As an individual that has always studied and worked in public health, including in both the private and public sectors, the research findings regarding the journey of EC in Brazil seemed very familiar and triggered many personal reflections.

As a spiritualist with a strong Catholic family background, I was forced to reconsider many bioethics and philosophical issues that intertwined with EC in Brazil. As a result, I acknowledge that my own awareness of the themes explored in this thesis were heightened. Moreover, as a student that has had the opportunity to live in Canada for the past three years, who has lived and studied the local health care system, I believe I acquired a unique perspective for comparison. The significant cultural, social, and economic differences between these two countries regarding women's rights and sexual health helped me realize the magnitude of the challenges that the Brazilian society faces with regard to women's rights advocacy.

Furthermore, the work I conducted in completion of my thesis convinced me that I want to dedicate my future efforts to help achieve the shift that is necessary in Brazil with regard to reproductive health care. I felt personally affected by the results of the research I conducted throughout my Master's project. I feel compelled to contribute to the advocacy of EC in Brazil, in order to disseminate correct and useful information to all women in Brazil that want and need it.

5.5 Statement of Contributions

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 conceptualized the study and completed the data collection and data analysis. I also led the writing of one research article. I was responsible for working with a team of aides to perform the trips to the 122 retail pharmacies and five libraries and archives in three different Brazilian cities. I also worked with an invaluable team to organize the results, perform data analysis, write, and edit this thesis in Canada.

Dr. Angel M. Foster served as my supervisor for the venture; she contributed to and was responsible for reviewing all components of the project, including conceptualization, study design, data collection, analysis, and manuscript development. Dr. Rayway Deonandan and Dr. Sanni Yaya participated as members of my Thesis Advisory Committee, providing essential feedback to shape and improve the project along the way.

5.6 Conclusions

This research aimed to explore the factors that shaped the incorporation of emergency contraception into the Brazilian health system and to assess current availability of progestin-only

ECPs. The results suggest that despite the fact that EC appears to be widely available, there are major barriers to its accessibility and there are a number of potential avenue to increase both availability and accessibility.

This study identified as main challenges the lack of relevant, accurate, and evidence-based information about EC among all stakeholders and the widespread misconception that progestin-only EC is a method to abortion. Socio-cultural and religious positions have influence the availability of EC in the public sector; although EC is available in retail pharmacies, the out-of-pocket costs combined with lack of awareness among both pharmacists and women serve as barriers to use.

The research about the journey of this medication in Brazil revealed that, despite being present since the 1990s, the great potential of ECPs to address a number of reproductive health concerns among both the overall population and among adolescents has not been realized. Despite a generally favorable national policy and regulatory environment, health-care providers and users still demonstrate a limited knowledge of its proper use and misinformation is fueled by organized opposition from the Catholic Church and broader social taboos.

Clearly, an effective way to improve access and availability is raising awareness among different stakeholders. Enhancing education initiatives for pharmacists and other health workers, developing targeted communications strategies focusing on potential users, and reviewing the sexual education curriculum in the country's school system should be governmental priorities. The society must encourage further discussions about reproductive health and disseminate accurate information about the available methods throughout the country. Further research in this area is essential as is renewed advocacy efforts dedicated to women's health-related issues in Brazil.

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Appendix A: Map of Brazil



Appendix B: Guidelines used to explore the history and evolution of EC

in Brazil

Brief history of the country-specific introduction of EC and its current status

- Who were the key players in its registration, procurement, and distribution?
- Who were the driving advocacy groups and stakeholders?
- What was the case-building process: research, community mobilization, engagement with religious or political leaders, support from the medical community?
- Was making EC available to sexual assault survivors part of the strategy and process?
- Were there major changes in the status of EC after initial introduction/registration (e.g., changes to BTC or OTC status)?

Public discussions and debates about EC

- How were the debates about EC framed?
 - o What was the overriding narrative used in the promotion of EC (e.g., public health, human rights, women's rights, etc.)
 - o Did the global/regional context influence the national debate? This could include debates and legal rulings in other countries, as well as research conducted in other settings.
- Did issues of 'culture' and/or 'religion' come into the public debates about EC?
- Was the science of EC discussed/debated?
 - o Did the scientific debates focus on mechanisms of action?
 - o Was the science/research politicized?
- Were public narratives/stories/archetypes about users of EC employed by either proponents or opponents of EC access?
 - o Who was the "public face" of EC?
 - o Did that "public face" differ between proponents and opponents?
 - o Why were these archetypes/narratives/stories/faces employed?
- Were men a part of the story/framing?
- How did the following groups respond to the introduction of and/or expansion of access to EC:
 - o Religious authorities/leaders
 - o The medical community (including pharmacists)
 - o Politicians/public policy decision-makers
 - o The media
 - o Women's groups/human rights groups
 - o Others
- Who was opposed to the introduction of EC and/or expanded access (if applicable) and what was the opposition based on?

Where are we now?

- Who is using EC? Where is it available? How much does it cost? Is it integrated into the health system(s)? Is access different for different groups of women?
- Is EC now included in national guidelines/norms
- Have the public debates/discussions about EC changed over time? In what way(s)?
- If the effort to introduce and expand EC required overcoming significant public debates and opposition, how was that accomplished?

What are the priorities moving forward?

- What are the most significant priorities in this country-specific context to expanding EC access?
- How might that expansion be accomplished in the years to come? What would be required?

Lessons learned

- What was unique about this country-specific experience?
 - o Was there a specific confluence of factors that provided a window of opportunity for introducing EC?
 - o Was there a specific moment/situation/champion of EC that impacted the introduction process?
- What lessons can we draw from this country's experience?
 - o Was there a particular sequence of events that could be replicated in other countries in the region? Elsewhere?
 - o Were there particular partnerships/coalitions that were especially important?
 - o Was there a frame or case-building research that could be replicated?
- What approaches "worked" and, in hindsight, what approaches might have worked better?

Appendix C: Mystery client profile

Mystery client profile

Maria is a 26-year-old woman who is visiting her fiancé (location altered per study site). She and her partner typically use condoms but did not do so when they had sex the night before.

Although she has never used emergency contraception, when she was in university she had friends who talked about “a pill” that was taken after sex to prevent pregnancy. She has no health problems or allergies and takes no medications on a regular basis. Her last period ended about a week earlier.