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Current Dispensing and Practice Use Patterns of Ulipristal Acetate (UPA) 30mg (Ella®), as Emergency Contraception in British Columbia, Canada

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Abstract:

Background: Ulipristal acetate 30 mg (UPA) became available as prescription-only emergency contraception in British Columbia, Canada September 2015, in addition to over-the-counter levonorgestrel emergency contraception. In this study, we determined dispensing patterns of UPA and facilitators and barriers for physicians, pharmacists, and patients to emergency contraception use in British Columbia.

Methods: The quantitative component of this mixed methods study determined UPA use between 09/2015 and 12/2018 in a database that captures all outpatient prescription dispensations in BC (PharmaNet) and market sales numbers for all emergency contraception in BC (IVQIA). We conducted semi-structured interviews exploring barriers and facilitators affecting UPA use from the perspectives of patients, community pharmacists, and prescribers. We performed iterative data collection and thematic analysis guided by Michie's Theoretical Domains Framework.

Results: Over the 3-year period 318 patients filled 368 UPA prescriptions. UPA use increased between 2015-2018. However, levonorgestrel use by sales (range: 118,897-129,478 units/year), was substantially higher than UPA (range: 128-389 units/year).

Analysis of 39 interviews resulted in the following themes and respective theoretical domain: (1) low awareness surrounding UPA (Knowledge) (2) beliefs about and experiences of shame and stigma were barriers to access (Beliefs about Consequences), and (3) multiple health system barriers exist to access emergency contraception (Reinforcement).

Interpretation: While there has been increase use of UPA, we identified multiple barriers to access. Opportunities for knowledge translation to improve use and access to emergency contraception and UPA in particular, include: curricular augmentation to address shame and stigma, advocating health policy for cost-free, prescription-free, and solely 'over the counter' emergency contraception.

Introduction

Ulipristal acetate 30 mg (UPA) became available as prescription-only emergency contraception in Canada September 2015. Emergency contraception prevents pregnancy by delaying ovulation after intercourse without contraception or contraceptive failure (1,2). UPA is superior to levonorgestrel emergency contraception in preventing pregnancy (3). UPA is more effective in overweight people and those 72 hours or more from intercourse (4,5). Accordingly, current Canadian practice guidelines recommend UPA for emergency contraception in people with BMI >25 kg/m² (e.g.) 45% of reproductive aged (18-34 years) females in Canada (5,6). There are currently no studies of UPA utilization in Canada.

Canadian research on emergency contraception has explored patient access barriers to levonorgestrel and counselling initiatives (7–11). In other countries, UPA is used less frequently than levonorgestrel; barriers include: limited awareness and misinformation surrounding emergency contraception and limited pharmacy capacity to immediately fill a UPA prescription due to geographic-specific policy regulations or no stock (12–26).

This study demonstrates dispensing patterns of UPA and levonorgestrel emergency contraception and explored facilitators and barriers to use with prescribers, pharmacists, and patients in British Columbia since 2015.

<u>Methods</u>

This mixed-methods study was conducted with concurrent quantitative and qualitative approaches (27). This study received ethical approval from the University of British Columbia Children's and Women's Research Ethics Board (H18-03350).

<u>Quantitative</u>: We measured emergency contraception use by combining prescription dispensations and pharmaceutical sales 09/2015-12/2018. We identified UPA prescriptions using PharmaNet, a populationbased database capturing all outpatient prescriptions dispensed in British Columbia, along with provider practice type. We obtained the volume of emergency contraception units sold to pharmacies from IVQIA, a market research firm. We calculated the number of prescriptions dispensed and sold to pharmacies per year for UPA and levonorgestrel sold separately. We calculated patient participant median age and the proportion of prescriber practice type and speciality for all dispensed UPA prescriptions. We conducted all quantitative analyses using R v3.5.3.

Qualitative: We recruited a purposeful sample of urban and rural participants for one-on-one semistructured interviews about knowledge, beliefs, and experiences with emergency contraception. We defined urban regions by Statistics Canada census metropolitan areas all other regions as rural (28). Patient eligibility criteria included age ≥18 years, at risk for pregnancy, and English communication. Inclusion criteria for health care included prescribers (physicians and nurse practitioners), community pharmacists, and nurses caring for people at risk for pregnancy. In order to explore potential barriers, we included nurses certified in contraceptive care who can provide contraception but cannot prescribe.

We recruited province-wide using gender, sexuality, and person-first materials (29). We recruited patients by provincial sexual health social media networks, pharmacists by faxing to community pharmacies, and prescribers through provincial practice e-networks. Recruitment materials linked to a REDCap intake survey confirming potential participants met inclusion criteria. We collected demographic data on each patient: age, body mass index, previous emergency contraceptive use.

Recruitment stopped once purposeful sampling was completed (30–33). Previous reviews note thematic saturation with purposeful sampling within twelve interviews (34).

MCC, a cis-female of colour feminist obstetrician/gynecologist, conducted all interviews and obtained verbal consent to participate in the study. We recorded interviews on a secure virtual conferencing platform. Participants received a \$50 gift card to acknowledge their contribution to the study.

We drew from Michie's Theoretical Domains Framework to develop an interview guide for patients and prescribers/pharmacists to explore constructs of behaviour change theories (30,33). A professional transcription service transcribed all audio recordings. Transcripts were cleaned to ensure deidentification and checked for quality/accuracy (MCC, FM). MCC led a hybrid inductive-deductive thematic analysis informed by a critical feminist reproductive justice lens (35,36). The primary author read and re-read the transcripts to gain familiarity with the data. MCC and SM generated a preliminary inductive codebook, and then deductively matched the codes to the Theoretical Domains. MCC coded three transcripts to test the preliminary codebook for fit and relevance and reviewed the coding with SM. They made minor revisions to the codebook for conceptual fit. MCC then coded all transcripts with the assistance of NVivo 12 Pro. Throughout we engaged in verification strategies including bracketing exercises, maintaining audit trail and field notes, and frequent team discussions of analysis in progress.

<u>Results</u>

Over the 3-year period 318 patients filled 368 UPA prescriptions: 281 filled one prescription, 26 filled two prescriptions, and 11 filled 3 or more. The mean age of UPA users was 29.8 years (SD = 7.7) 25% were younger than 24 while 25% were older than 35. Prescribers included 354 physicians (18 (5%) were OB/GYN specialists) and 9 nurse practitioners. UPA medication dispensed to patients and purchased by pharmacies increased (Table 1). Levonorgestrel use by sales (range: 118,897-129,478 units/year), was substantially higher than UPA (range: 128-389 units/year).

We interviewed 12 patients, 12 prescribers, 12 pharmacists, and 3 nurses. Patient median age was 27 years and half had a BMI over 25kg/m². All pharmacists and prescribers reported experience with levonorgestrel, but only a third with UPA. The qualitative analysis identified more barriers than facilitators to emergency contraception use. However, because there was such low awareness of UPA, we could not compare barriers and facilitators to UPA and levonorgestrel separately.

We identified 3 core themes mapped to the Theoretical Domains Framework of: knowledge, beliefs about consequences, reinforcement.

1. There was low awareness surrounding UPA (Knowledge).

The knowledge domain defines as awareness of the existence of something. The absence of awareness led to low knowledge resulting in barriers to UPA. Patients were aware of levonorgestrel availability at a pharmacy. However, many were unaware of UPA or the need for a prescription. Patients were aware emergency contraception use to prevent pregnancy after intercourse. Patients demonstrated limited understanding of how emergency contraception works, and some feared it would be harmful or dangerous, as explained:

"My understanding is if you were to have unprotected sex or. . . reason why you would think that you might get pregnant, the next day you would take the pill. I understand that it hurts your body a little bit.

You get quite sick. . . And, yeah, that nobody really wants to take it because it kind of makes you a little bit sick" (R63, patient)

When asked about awareness and knowledge of emergency contraception, patients perceived a dearth of comprehensive sexual education contributing to low reproductive health literacy:

"I think everybody should have sex education and I know not everybody in B.C. has access to . . . sexual education. . . But I think that any time somebody's talking about contraceptives or sex or sexual health or sexuality to youth in schools, I think there needs to be a conversation that's age appropriate, when they start talking about contraception to be talking about emergency contraception as well." (R17, patient)

Prescribers and pharmacists acquired knowledge on emergency contraception in didactic training or exposure in practice. In practice, prescribers perceived continuing professional development as self-directed. They reported challenges to know what is newly available, such as UPA, unless spurred by a clinical encounter.

"Just the need to know about what's up to date and particularly like I said, because I don't recall recently having anybody come in and actually asking me for it." (R40, prescriber)

Prescribers referenced clinical practice guidelines by the Society of Obstetricians and Gynecologists of Canada (SOGC) as the standard of care. However, they described barriers to knowledge acquisition, such as gated access to the SOGC's resources and guidance.

"I mean, a lot of societies are like that. . . previously we could read the whole guideline and then we were limited to just reading the highlights and then recently we were just not allowed." (R56, prescriber)

2. Beliefs about or experience of shame and stigma (Beliefs about Consequences)

Our analysis of interviews indicated shame and stigma were barriers to access. This mapped to the theoretical domain of beliefs about consequences, defined as the acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use.

Patients shared beliefs and feelings of shame surrounding potential reasons for needing and when accessing emergency contraception, for example:

"Because I really feel that there's a sense of you only take this if you really screwed up this time" (R30, patient)

"I think when it comes to having something that somebody would need an emergency contraceptive for it can be even more shaming. Like why didn't you use this. Why didn't you use that. How come you're not using the pill. How come you're not using a condom." (R17, patient)

"I think it's a problem people encounter while getting it. So the outcome of having the medication is still the same. But people feel bad about it after because of attitudes that they met from . . . filling the prescription." (R23, patient)

Prescribers and pharmacists shared opinions on acceptable emergency contraception use. The following examples illustrated beliefs:

"First of all if you're sexually active it [EC] shouldn't be your main source of contraception. But obviously accidents do happen, and when those happen, then that should be an option for you and I will be willing to provide you that care." (R51, pharmacist)

"I think that it should be sort of a last-ditch thing. . . it shouldn't be used all the time. . . I mean, normally I'm totally happy to dispense it. I don't want there to be unwanted pregnancies, unwanted abortions, unwanted children. But I sometimes feel like there should be a little bit more preparation done." (R52, pharmacist)

Patient participants expressed feelings of shame for needing emergency contraception. Patient lived experience and health care provider beliefs on acceptable emergency contraceptive use can contribute to reinforcing perceived shame beliefs by patients.

3. Health care system barriers (Reinforcement)

We identified multiple health system barriers for patients seeking emergency contraception, including prescription, 'behind the counter' access, limited supply due to perceptions of low demand, and cost. These barriers mapped to the theoretical domain of reinforcement: encouraging a behaviour through positive or negative stimulus.

Patients identified prescription status for UPA a barrier: needing to take time away from work, finding transportation or waiting unpredictable walk-in clinic hours.

"If I had two options, one was a prescribed pill and one was an over the counter pill, I would go for the over the counter pill. Because I don't want to book an appointment with my doctor to go get the prescription, to then go to the pharmacy to pick up the medication. I just want to go directly to the pharmacy and get the pill." (R19, patient)

We identified 'counter status': where emergency contraception is physically located a barrier. Although levonorgestrel is "over the counter" pharmacists often keep it "behind the counter" to reinforce medication safety and patient counselling. From the patient's perspective, this practice inadvertently reinforced access barriers and did not consider patient-identified characteristics of 'safety': privacy, mental wellness, avoiding shame or stigma. As one pharmacist described:

"[We place it] behind the counter, so we want to make sure we don't miss anything. So even if someone come to the counter request emergency contraception, the pharmacist will automatically provide counselling to the patient. . .We dispense medication. And we have to provide counselling of everything that leaves the drugstore. Every kind of medication we provide counselling. And the counselling is done by the pharmacist." (R111, pharmacist)

Pharmacist duty to counsel was in tension with patients' reported desire for privacy and minimal contact to mitigate shame and stigma:

"Someone might be really embarrassed to be in the pharmacy. . . I know it's my experience of feeling embarrassed to be inside the pharmacy and want to get out as quickly as possible. Don't want to look at the pharmacist. You just want to get your pill and leave." (R16, patient)

Many pharmacists reported that their pharmacies did not regularly stock UPA because of perceived low demand and concerns about the costs of expired product to their business:

"But for sure if the government allows ulipristal to be also prescribed by pharmacists then I think in general pharmacy is—it's a business. So they would do whatever that would make them money. So if they think that increasing the awareness of this new birth control pill that's effective for five days after rather than three days after, and more girls are aware of it and they kept—more girls are asking for it, then they would see it as a business opportunity. Then that would be what would make them, like, advertise or—to advocate for the change." (R31, pharmacist)

All participants cited cost as a barrier to emergency contraceptive access, patient emphasized:

"I think cost being the big one" (R17, patient).

Taken together, diverse health system barriers impacted access to emergency contraception and patients' help-seeking behaviours. Although UPA may be a superior option for preventing pregnancy, multiple barriers exist to access relative to over-the-counter levonorgestrel.

Interpretation

Since availability of UPA emergency contraception, there has been an increase in the number of units sold and dispensed, compared to stable levonorgestrel sales. Despite current guidance from the Society of Obstetrics and Gynecology, levonorgestrel continues to be sold more frequently than UPA.

All participants identified low awareness of UPA, consistent with previous studies (19,21). Australian and European studies similarly found that UPA was not frequently supplied or sold due to lack of clinical knowledge and new market status (14,26). Our findings suggest a need to increase awareness and knowledge to optimize clinically recommended UPA use.

Shame and stigma are determinants of health outcomes and health inequities, particularly in reproductive health. People who experience stigma have poorer health outcomes because of adjusted help-seeking behaviour (37). Our analysis illustrates patient experienced stigma and shame in accessing emergency contraception: a patient avoids pharmacy counselling with subsequent mistimed emergency contraception use. Patient experiences may have been in reaction to health care perception of emergency contraception as a last resort for preventing pregnancy and emergency contraception use only if they *"really screwed up."* To facilitate implementation of UPA in routine contraceptive care, it is critical to address beliefs about shame and stigma.

We identified multiple barriers in patient access to emergency contraception consistent with previous secret shoppers studies observing similar difficulties (16–18). Our results offer a refined understanding of 'counter status' barrier – the desire to avoid shaming and limit social contact were salient to patients while pharmacists held concerns about their duty to provide safe medication counselling. The cost of medication is a known barrier, prior research found people from affluent areas were significantly more likely to use emergency contraception to prevent pregnancy than individuals from less affluent areas (38). Our results further identified that pharmacists were concerned about the cost to their business of expired stock in the event of low consumer demand.

Study strengths included population-based prescription dispensation data and diverse research advisory team included diverse expertise. Limitations included no guarantee people take medications dispensed and no provincial BMI data.

<u>Conclusion:</u> We found increased UPA and stable levonorgestrel use from 2015-2018. We identified multiple barriers to access: low awareness of UPA, perceived and experienced shame and stigma, and health systems barriers reinforcing challenges to access emergency contraception. There is potential to optimize recommended clinical practice with comprehensive sexual education and health care curricular augmentation addressing stigma to normalize emergency contraception access. At a health system level, it is critical to move towards cost-free, prescription-free and solely 'over the counter' emergency contraception to improve patient-centred access and evidence-based care.

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Tables & Figures

Table 1 – PharmaNet dispensation and IVQIA sales 2015-2018 in British Columbia

Year	PharmaNet Data IVQIA Data		Data
	UPA Dispensed	LNG	UPA
2015*	<5	56 021	44
2016	48	129 478	128
2017	149	118 897	195
2018	167	124 910	389

*2015 only includes Sept-Dec rather than the full year

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