



Editor's Choice

Barriers to Single-Dose Levonorgestrel-Only Emergency Contraception Access in Retail Pharmacies



Van (Mimi) Chau, BA^{a,*}, Carol A. Stamm, MD^{a,b,c},
 Laura Borgelt, Pharm D, FCCP, BCPS^d, Michelle Gaffaney, BA, MPAS, PA-C^a,
 Alia Moore, MD^a, Rachel Z. Blumhagen, MS^e, Leanne Rupp, MSW, LCSW^{b,c},
 Daniel Topp, MA^{b,c}, Christine Gilroy, MD, MSPH^{a,f}

^a Division of General Internal Medicine, University of Colorado School of Medicine, Aurora, Colorado

^b Department of Obstetrics and Gynecology, University of Colorado School of Medicine, Aurora, Colorado

^c Uptown Primary Care, Denver, Colorado

^d Departments of Clinical Pharmacy and Family Medicine, University of Colorado Skaggs School of Pharmacy and Pharmaceutical Science, Aurora, Colorado

^e Department of Biostatistics and Informatics, Colorado School of Public Health, Aurora, Colorado

^f Department of Pediatrics, University of Colorado School of Medicine, Aurora, Colorado

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A B S T R A C T

Objectives: In February 2014, the Food and Drug Administration updated its regulations to make all single-dose levonorgestrel-only emergency contraception (LNG-EC) available over the counter. This study examines the availability and access to LNG-EC shortly after this policy change, and any additional barriers to obtaining LNG-EC in Colorado retail pharmacies.

Study Design: From June to July 2014, three female interviewers posing as women seeking LNG-EC conducted a telephone survey of all 633 Colorado retail pharmacies listed in *The Little Blue Book* (2014) phone directory. Completely accessible was defined as LNG-EC available on store shelves for purchase without presentation of an ID or prescription on the day of the call.

Results: Of 633 pharmacies analyzed, 85.0% (538/633) were in urban settings and 85.3% (540/633) were chain stores. Eighteen of 64 (28.1%) counties in Colorado did not have a pharmacy listed in the phone directory. Overall, 86.9% of pharmacies (550/633) had EC in stock on the day of contact but only 23.2% (147/633) of these had EC completely accessible. Of pharmacies with EC in stock, 41.6% (229/550) kept it behind the counter and 56.0% (308/550) required additional documentation to purchase. In stock and completely accessible rates were not different across rural, urban, and frontier geographic regions within the state ($p = .066$ and $p = .905$, respectively), but were significantly different across independent, chain, and 24-hour type stores ($p < .001$ and $p = .008$, respectively). In stock rates were 57.5% (42/73), 90.4% (488/540), and 100% (20/20) for independent, chain, and 24-hour stores respectively.

Conclusions: Rates of completely accessible LNG-EC are low in Colorado despite high rates of availability. Behind-the-counter status and proof-of-age requirements are identified as the main sources of access restriction in Colorado.

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Emergency contraception (EC) describes any contraceptive method that prevents pregnancy after unprotected or under-protected sexual intercourse (Trussell, Raymond, & Cleland, 2014; American College of Obstetricians and Gynecologists, 2010; World

Health Organization, 2012). Single-dose levonorgestrel-only (LNG) pills are currently the only forms of EC available over the counter (OTC) and include the brand name Plan-B One-Step and generic options such as Take Action. The most likely mechanism of action for these products is inhibition or delay of ovulation, and they are most effective if taken within 120 hours of sexual intercourse (Gemzell-Danielsson, Berger, & Lalitkumar, 2013).

In May 1999, the Food and Drug Administration (FDA) approved brand-name Plan B for women with a prescription (Office of Population Research, 2016). In August 2006, Plan B

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* Correspondence to: Van (Mimi) Chau, BA, University of Colorado School of Medicine, 13001 E 17th Place, Aurora, CO 80045. Phone: 303-886-6458.

E-mail address: van.t.chau@ucdenver.edu (V.(Mimi) Chau).

became available OTC for consumers aged 18 years and older, although those aged 17 years and younger still needed a prescription to purchase. In 2009, the age restriction dropped to 17 years of age, and finally in June 2013, Plan B One-Step became available OTC without an age restriction. In February 2014, generic LNG-EC was approved for OTC use, effectively making all single-dose LNG-EC products potentially accessible for anyone to purchase without proof of age or prescription (Butler, 2013).

However, accessibility barriers such as high cost (Cleveland, 2013; American College of Obstetricians and Gynecologists, 2012), low pharmacy stock rates (Chuang and Shank, 2006; Samson et al., 2012), and geographic distance to a pharmacy (NARAL, 2010) may still exist. The primary aim of this survey was to identify and quantify the barriers to access encountered by female consumers purchasing LNG-EC in Colorado retail pharmacies, including distance to pharmacies, identification requirements, and behind-the-counter status.

Methods

Three researchers, posing as women seeking LNG-EC, completed a telephone survey of Colorado retail pharmacies from June to July 2014. Pharmacy contact information was obtained from a phone directory titled *The Little Blue Book 2014* (Sharecare, 2014). Pharmacies voluntarily list their information in this reference guide, which is predominantly used by physicians for referrals. Although comprehensive, it does not represent a complete list of all pharmacies in Colorado. The analyzed sample size only included operating retail pharmacies serving the general public; compounding, inpatient, psychiatric, and permanently closed pharmacies were excluded. Pharmacies were categorized in two ways: by pharmacy type (chain, independent, or 24-hour store) and location (urban, rural, or frontier county). Chain pharmacies are those belonging to a public corporation, and share a centralized brand. Independent pharmacies comprise stores that are locally and privately owned. Twenty-four-hour pharmacies were all part of chain companies and open at all hours. Geographic county categorizations were applied using definitions provided by the Colorado State Office of Rural Health (Colorado Health Institute, 2014). Urban counties comprise areas with a core metropolitan area of 10,000 people or more, rural counties are those without a metropolitan core, and frontier counties are defined as having six or fewer persons per square mile.

The structured survey script contained an introduction about a woman seeking LNG-EC. The researcher asked about the role of the pharmacy employee and was allowed to make assumptions about his or her gender. Further questions included availability of LNG-EC on the day of the call (in stock status), location of product (on shelf or behind the pharmacy counter), availability of generic products, cost, and the need for additional documentation to purchase (proof of age and/or prescription). When the pharmacy did not have LNG-EC in stock, questions about alternative venues to obtain LNG-EC, ability to order the product, cost, whether or not the store typically carried LNG-EC, and where it was normally stocked within the store (shelf or behind pharmacy counter) were asked.

In stock was defined as having LNG-EC available for purchase on the day of contact. Completely accessible was defined as LNG-EC being in stock, on the shelf, and available for purchase without additional documentation. Researchers called pharmacies as many times as necessary to contact a pharmacy employee. If an employee hung up before the survey could be completed,

the encounter was categorized as unable to assess. In these instances, pharmacies did not receive a call back. If calls were dropped owing to poor cellular reception or if the research assistant forgot to ask a question before ending the call, the pharmacy received a call back. All surveys that included the in stock variable were included in the analysis, regardless of which additional variables were addressed. All calls were made on two cellular phones purchased for the study that were not linked to any institution. Personal identities of the callers and research intentions were not disclosed.

All data were collected and recorded on paper, managed using the REDCap electronic data capture tool (Harris, Taylor, Payne, Gonzalez, & Conde, 2009) and verified by an additional research assistant for accuracy. The protocol was approved by the Colorado Multiple Institutional Review Board.

Rates of in stock, completely accessible, availability of generics, and additional documentation requirements were summarized with frequency and percent, and compared by geographic region and pharmacy type using χ^2 tests with Fisher's exact testing when asymptotic assumptions were not met. The analysis was conducted using SAS/STAT Software (SAS Institute, Cary, NC).

An a priori power calculation was performed using the assumption that 90% of the pharmacies in *The Little Blue Book* (2014; $n = 621$) were included in the sample and were distributed as 85% chain, 10% independent, and 5% 24-hour type. Assuming a type I error rate of 0.05 and the proportion of chain pharmacies with EC in stock is 50%, the analysis has 80% power to detect a difference of 18.4% between chain and independent pharmacies and a 24.9% difference between chain and 24-hour pharmacies. Given the distribution of pharmacies across geographic regions is comparable to that of pharmacy types (~85% urban, ~10% rural, and ~5% frontier), the analysis is also powered to detect the same differences between in stock proportions for urban versus nonurban areas. Power calculations were performed using G*Power Version 3.1.9.2 (Faul, Erdfelder, Lang, & Buchner, 2007).

Qualitative data, including pharmacy comments regarding access and researcher comments on customer service quality, were also recorded but not analyzed for this article.

Results

Of 690 pharmacies identified in Colorado, 633 (91.7%) were surveyed. Of those excluded pharmacies, 39 of 57 (68.4%) were permanently closed and 18 of 57 (31.6%) were either compounding, psychiatric-only, or hospital-based pharmacies. There were 18 of 64 Colorado counties (28.1%) that did not have a pharmacy listed in the phone book. At 17 of 633 pharmacies (2.6%), employees indicated the status of LNG-EC stock, but hung up before the survey could be completed.

Of the pharmacies included in the analysis, 85.0% (538/633) were in urban areas and 85.3% (540/633) were chain stores. Ninety-five pharmacies (14.5%; 95/655) were found in rural and frontier areas. Of the pharmacies in these areas, 21 (22.1%; 21/95) were independent stores. Most employees answering the phones were pharmacy technicians (59.1%; 374/633) and women (70.9%; 449/633; Table 1).

Most pharmacies (86.9%; 550/633) carried LNG-EC on the day of contact (i.e., in stock; Table 1). In stock rates were 57.5% (42/73), 90.4% (488/540), and 100% (20/20) for independent, chain, and 24-hour stores, respectively ($p < .001$). In stock rates were 85.9% (462/538), 94.9% (75/79), and 81.3% (13/16) for urban,

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