

Original Research Article

Pharmacy availability of emergency contraception in southwestern Pennsylvania: A simulated patient study[☆]Katherine Orr^a, Jennifer Chin^{b,*}, Maris Cuddeback^a, Jessica Zimo^a, Colleen Judge-Golden^{a,c}, Marian Jarlenski^c, Sonya Borrero^{c,d,e}^a University of Pittsburgh School of Medicine, Pittsburgh, PA, United States^b Department of Obstetrics and Gynecology, University of Washington, Seattle, WA, United States^c Center for Women's Health Research and Innovation, University of Pittsburgh, Pittsburgh, PA, United States^d Department of Medicine, University of Pittsburgh, Pittsburgh, PA, United States^e Center for Health Equity Research and Promotion, VA Pittsburgh Healthcare System, Pittsburgh, PA, United States

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ABSTRACT

Objective: To assess the availability of oral emergency contraception in southwestern Pennsylvania pharmacies.**Study design:** We conducted a simulated patient study to assess on-the-shelf availability of levonorgestrel emergency contraception and immediate availability of ulipristal acetate emergency contraception.**Results:** Only 44% of pharmacies stocked levonorgestrel on-the-shelf and only 5% of pharmacies had ulipristal acetate immediately available.**Conclusions:** We found significant barriers to obtaining timely oral emergency contraception in southwestern Pennsylvania.**Implications statement:** Timely access to emergency contraception is important for people's ability to determine if, when, how, and under what circumstances to have children. Pharmacies in southwestern Pennsylvania need to expand access to oral emergency contraception.

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1. Introduction

Oral emergency contraception (EC) can prevent pregnancy after an episode of unprotected sexual intercourse. Two types of pills, levonorgestrel (LNG) and ulipristal acetate (UPA) are specifically packaged for use as EC. UPA is more effective than LNG, especially for overweight and obese women and between 72 and 120 hours after unprotected intercourse [1,2]. EC is widely used, with 23% of people in the United States reporting using it at least once to prevent pregnancy and 45% of those who have ever used EC using it more than once [3]. Though both medications are safe, effective, and well tolerated, access to both is hampered by pharmacy availability and stocking practices [4,5].

While LNG is currently available for over the counter (OTC) purchase for all ages without a prescription, its US Food and Drug Administration (FDA) approval history has been arduous and char-

acterized by numerous regulatory changes. In 1999, the FDA first approved the brand name Plan B for emergency contraception by prescription only. In 2006, the FDA approved it for OTC sale but only to those 18 years and older; the age restriction was lifted in 2013. In 2014, the FDA further approved generic brands of LNG to be sold OTC. In contrast, UPA, which was approved for use by the FDA in 2010, requires a prescription for purchase [6].

Although these 2 products have been now been available for over a decade, numerous barriers to access for both remain. A study conducted in Hawaii in 2018 found that only 84% of pharmacies had LNG readily available for purchase OTC [4]. A study conducted in 2018 to 2019 in South Texas found that only 2.6% of pharmacies had unrestricted LNG OTC access, meaning in-stock, directly available for purchase on the store shelf, and with no security barriers such as a locked cabinet or an individual locked container [7]. As for UPA, 2 studies conducted in 2018 and 2019 found that less than 10% of pharmacies routinely stock it for immediate access, with commercial pharmacies more likely to carry UPA than independent pharmacies [5,8].

A previous telephone survey study conducted in Pennsylvania in 2006 found that LNG was available in only 32% of pharmacies,

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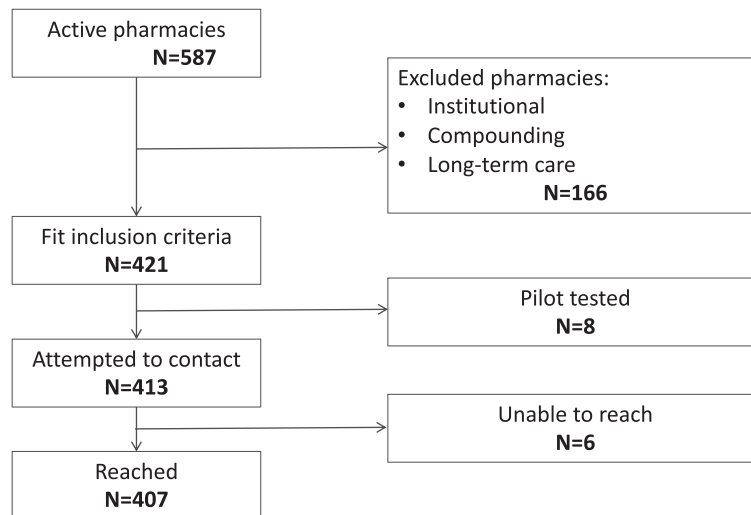


Figure. Figure: Inclusion/exclusion criteria for pharmacies in southwestern Pennsylvania in 2018.

with no differences in rural and urban locations [9]. As this study was conducted prior to the approval of UPA and relaxation of LNG sales, we aimed to assess the availability of LNG and UPA in southwestern PA, which is primarily made up of rural counties with an urban center (Pittsburgh), using a simulated patient model.

2. Materials and methods

We employed a simulated patient model to assess the availability of EC in retail pharmacies in southwestern Pennsylvania including Allegheny county and its five contiguous counties. We generated a census of all pharmacies ($N = 587$) in the 6 counties using the PA Department of State licensing website [10]. Our inclusion criteria were retail pharmacies open to the public that carried prescription and OTC medications. We excluded compounding, long-term care, and institutional pharmacies for a total of 421 pharmacies, as shown in the Figure.

We further classified pharmacies by location (rural vs urban) and type (chain vs independent). We based location designations on the Center for Rural Pennsylvania, which defines a rural county as a population density of less than 284 persons per square mile [11]. We included rural counties Armstrong, Butler, and Washington and urban counties Beaver, Westmoreland, and Allegheny. For pharmacy type, we used the American Pharmacists Association definition, in which pharmacies with 3 or fewer locations are considered independent [12].

Our study had 2 arms. The first was an in-person assessment of on-the-shelf availability of LNG at a stratified random sample of 80 pharmacies. We selected these pharmacies by grouping our included pharmacies into 4 categories (urban chain, urban independent, rural chain, and rural independent) then randomly sampling approximately 20 pharmacies from each group. The second arm was a telephone survey of all 421 retail pharmacies in the 6 counties to assess immediate availability of UPA.

For both arms of the study, we developed and piloted a standardized script. All pharmacy visits and calls occurred between June and August 2018. In both arms, research staff specifically asked to speak with the pharmacist. Research staff were female-presenting individuals of reproductive age.

For the in-person arm, our primary outcome was on-the-shelf access to LNG, and our secondary outcome was overall availability. Two study team members visited each pharmacy together. The first represented herself as a shopper seeking “the morning-after pill,”

while the second investigator completed an online data collection form.

For the telephone arm, our primary outcome was immediate availability of UPA and our secondary outcome was next day availability of UPA. Research staff represented themselves as patients seeking to fill a written prescription for UPA. If told it was not in stock, the investigator asked if it could be ordered for the next day. We made 3 call attempts on different days before a pharmacy was deemed unreachable.

We used descriptive statistics to analyze the primary and secondary outcomes. We used chi-square tests to detect bivariate associations between our outcomes and the pharmacy characteristics (rural vs urban; independent vs chain). The University of Pittsburgh Institutional Review Board determined this study to be nonhuman subjects research.

3. Results

Results are shown in the Table. For our in-person arm assessing availability of LNG, we visited 72/80 pharmacies for a contact rate of 90%. Overall, only 30 (42%) pharmacies stocked LNG on-the-shelf, 19 (26%) kept LNG behind the counter, and 23 (32%) did not have LNG in stock at all. The majority (70%) of pharmacies that had LNG on-the-shelf kept the product in a locked box. Chain pharmacies were more likely than independent pharmacies to have LNG on-the-shelf (61% vs 16%, $p < 0.001$) and were also more likely to have LNG available (83% vs 48%, $p = 0.002$). Urban pharmacies were as likely as rural pharmacies to have LNG on-the-shelf (34% vs 50%, $p = 0.17$) and had similar rates of overall availability (68% vs 68%, $p = 0.9$).

For our telephone arm assessing availability of UPA, we contacted 407 of the 413 eligible pharmacies, yielding a contact rate of 99%. Overall, only 21 (5%) of pharmacies had UPA immediately available and 174 (43%) were able to order it for the next day. UPA was exclusively available at urban chain pharmacies. Nearly half of pharmacists who were contacted ($n = 182$, 45%) spontaneously reported that they had never heard of UPA, although knowledge of UPA was not a question in the simulated patient script.

4. Discussion

This patient simulated study identified an urgent need to expand pharmacy availability of LNG and UPA in southwestern PA. Less than half of pharmacies stocked LNG on-the-shelf, and most

Table

Availability of Levonorgestrel and Ulipristal Acetate Emergency Contraception in Southwestern Pennsylvania Pharmacies in 2018.

Levonorgestrel				
Pharmacy type ^a	Urban chain (N = 22)	Urban independent (N = 16)	Rural chain (N = 19)	Rural independent (N = 15)
Available today.	18 (82)	8 (50)	16 (84)	7 (47)
Location				
On the shelf	1 (5)	2 (13)	3 (16)	3 (20)
On the shelf in locked box.	10 (45)	0	11 (58)	0
Behind the counter	6 (27)	6 (38)	3 (16)	4 (27)
Ulipristal acetate				
Pharmacy type	Urban chain (N = 276)	Urban independent (N = 48)	Rural chain (N = 65)	Rural independent (N = 18)
Available today	21 (8)	0	0	0
Can order for tomorrow	116 (42)	24 (50)	30 (46)	4 (22)

Data presented as n (%).

^a Pharmacy types are not evenly distributed as there were not an equal number of pharmacy types available for contact.

of them kept LNG in a locked box, making it difficult for patients to buy EC discreetly. Only a few pharmacies had UPA available for same day purchase, all of which were in urban locations.

Although overall EC use has increased since FDA approval of OTC sale [6], pharmacy access remains a common problem throughout the US [4,13]. Barriers to EC pharmacy availability are varied, including suboptimal stocking due to perception of low demand, pharmacy staff personal objection, or placing OTC EC behind the counter or in a locked box due to concerns about theft [14]. Our findings are consistent with other studies showing that a high proportion of pharmacies choose to keep LNG in a locked box or cabinet, complicating the OTC nature of this medication [7]. Moreover, almost half of pharmacists in our study spontaneously reported that they had never heard of UPA when asked about obtaining this medication. Because we only recorded this variable when volunteered, this may be an underestimate of pharmacist knowledge of UPA. Given the time sensitive nature of oral EC, pharmacies should facilitate unrestricted same day access to both LNG and UPA. Pharmacies and pharmacy staff can play a role in helping to reduce the stigma and shame many patients, especially adolescents, experience when purchasing oral EC by facilitating discreet and efficient purchases.

Our study has several limitations. First, our assessment was limited to southwestern Pennsylvania, so results may not be generalizable to other areas. Second, due to the simulated patient methodology, we were unable to determine pharmacies' reasons for not offering UPA or how they decided to stock LNG. Third, study staff asked to speak directly with a pharmacist, which may not necessarily replicate real-world behavior; thus our results may indicate higher access than actually exists for patients who speak with nonpharmacist staff members. Finally, we did not assess cost barriers that could arise due to lack of health insurance, the fact that OTC LNG purchase is not always reimbursable through insurance, and/or denial of insurance coverage due to religious exemptions.

Same-day access to oral EC is essential for people's ability to prevent pregnancy. In light of the COVID-19 pandemic, barriers to EC have only increased due to quarantine measures, financial insecurity, and childcare issues [15]. Women's health organizations have stated that access to continuous contraception and EC is a priority for reproductive health during the pandemic [16]. Pharmacies must do their part to ensure that people have timely access to these essential medications to support their ability to determine if, when, and under what circumstances to have children.

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