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Access to Emergency Contraception in the Over-the-Counter Era

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Abstract

Introduction—After years of complex regulatory changes, levonorgestrel emergency contraception (LNG EC) is now approved for unrestricted sale in the US. Timely access to EC pills is critical because they are more likely to work the sooner they are taken. This study assesses whether LNG EC is sold in accordance with current Food and Drug Administration regulations.

Methods—We distributed an online questionnaire through an EC-focused listserv for reproductive health professionals, asking data collectors to visit local stores and document product names, price, over-the-counter (OTC) shelf availability, and misinformation about age restrictions. We used Chi-square analysis to assess bivariate associations and t-tests and Wilcoxon rank-sum tests to determine differences in means.

Results—We collected information about 220 stores. The majority (65%) stocked EC on OTC shelves, although only 22% of these displayed it without a locked security enclosure. Chain pharmacies were more likely to shelf-stock EC than independent pharmacies (77% vs 5%; $p=0.000$), but variation existed among stores within the same chain. Among stores that were asked, 40% incorrectly reported an age restriction for non-prescription purchase of LNG EC, while 95% correctly reported that men can buy LNG EC. The average price of branded and generic LNG EC was \$49.64 and \$40.05, respectively.

Conclusion—Changes in the regulatory status of LNG EC have resulted in widespread confusion about how EC can be sold, and its high price contributes to access barriers. Retailers should ensure that consumers can access LNG EC quickly and easily by stocking the product on OTC shelves and educating staff about current regulations.

Introduction

Emergency contraceptives are medications or devices that are used after intercourse to reduce the risk of pregnancy, providing women with a last chance to prevent unintended

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pregnancy after unprotected sex, contraceptive failure, or coerced intercourse (Trussell, Raymond, & Cleland, 2014; World Health Organization, 2012). The most effective form of emergency contraception (EC) is the copper IUD, which is nearly 100% effective in preventing pregnancy after unprotected sex and provides at least 12 years of excellent ongoing contraception (United Nations Development Programme, et. al., 1997), but use of this form of EC is limited by cost, logistical challenges, acceptability, and awareness (Cleland, Zhu, Goldstuck, Cheng, & Trussell, 2012). Combined oral contraceptive pills in larger doses were used as emergency contraception (EC) in the United States for nearly twenty years before dedicated EC pills became available in the late 1990s. EC pills are a time-sensitive treatment; although some evidence shows that they can work for up to 120 hours (Dada, Godfrey, Piaggio, von Hertzen, & Nigerian Network Reprod Hlth Res &, 2010; Fine et al., 2010; Glasier et al., 2010; Ngai, Fan, Li, Cheng, & Ding, 2004; von Hertzen et al., 2002), EC pills should be taken as soon as possible because they work by inhibiting ovulation (Gemzell-Danielsson, Berger, & Lalitkumar, 2013). It is often difficult for women to know precisely where they are in their cycle, and if ovulation is imminent, a woman may not have 120 hours to wait. Any barriers that stand in the way of timely access to EC can put women at substantial risk of pregnancy.

There are now two types of dedicated pills available in the US: ulipristal acetate (UPA) and levonorgestrel (LNG). Although UPA is preferable in most situations because it is more effective than LNG (Glasier et al., 2010), UPA can be difficult to access. UPA EC is a prescription-only product, and awareness and provision of this option are low among healthcare providers (Batur et al., 2016). In addition, availability of UPA in pharmacies may be extremely limited: in a recent study of all pharmacies in Hawaii, only 2.6% had UPA immediately available, while 82.4% had LNG EC in stock (Bullock et al., 2015). LNG EC may be the only option available to many women within the short timeframe in which EC is effective; therefore, assessing and improving the accessibility of LNG is an important objective.

The regulatory history of EC pills in the US has been surrounded by much debate and controversy, which have created unnecessary barriers to accessibility (Wynn, 2012). The first LNG EC pill was initially approved in 1999 as a two-dose prescription-only product and, despite the overwhelming evidence of the safety of the drug for women of all ages (Harper, Weiss, Speidel, & Raine-Bennett, 2008), it remained prescription-only until 2006. In 2006, LNG EC was approved for non-prescription sale to women and men aged 18 years or older, and three years later the age limit for non-prescription sale was lowered to 17 years (Wynn, 2012). Younger women still required a prescription and this dual status meant that the medication was held behind the pharmacy counter so that the age restriction could be enforced. In addition to the burdens placed on young women to obtain a prescription, the required interaction with pharmacy personnel and the need to present identification created barriers for women of all ages (Hickey & White, 2015; Rafie et al., 2013). The branded LNG EC product, Plan B One-Step[®], was approved for unrestricted sale in 2013, but the age-restricted label remained in place for its generic equivalents until 2014.

After years of complicated and politically fraught regulatory changes, current Food and Drug Administration (FDA) regulations now allow all one-dose LNG EC to be sold without

identification requirements or point-of-sale restrictions to women and men of any age. Two-dose LNG EC remained available under dual status, without prescription for women aged 17 and older and with prescription for women younger than 17. As of April 2016, two-dose LNG EC products are no longer marketed in the US. As a result, all one-dose LNG EC products may be stocked on over-the-counter (OTC) shelves and do not need to be held behind the pharmacy counter. However, the frequent changes to the age restrictions on the non-prescription sale of LNG EC contributed to wide-spread confusion about the regulatory status of the product. Further complicating understandings about age restrictions was the use recommendation (“For women 17 years of age and older”) listed on packages for generic LNG EC products sold by companies other than the owner of the branded product. This language was in place (until April 2016) to protect the company’s OTC market exclusivity for the branded product. While it was not an enforceable age restriction, this language (in addition to the presence of two-dose LNG EC products bearing the dual label) may have confused the question of eligibility for OTC purchase. Several studies have assessed the state of access to LNG EC in recent years (Bell, Camacho, & Velasquez, 2014; Hickey & White, 2015; Wilkinson, Vargas, Fahey, Suther, & Silverstein, 2014), but none has been published since the approval of all one-dose LNG EC for OTC sale without age restrictions. This study describes the state of access to fully OTC LNG EC.

Materials and methods

In the summer of 2015, we distributed a standardized online questionnaire through the listserv for the American Society for Emergency Contraception, which includes more than 1,000 members and partner organizations. We asked colleagues to collect data at local stores of their choosing and use the questionnaire to document the characteristics of how LNG EC was being sold, including product names, price(s), and whether the product(s) was available on an OTC shelf or only behind the pharmacy counter. Some of the stores are primarily pharmacies, while others are grocery or “big box” stores (large chain stores that sell a variety of products), but all had a pharmacy section. In our analyses, we coded a store as stocking EC “on the shelf” if the product was visible in an OTC store aisle and not behind a counter. This included stores in which the product was available directly on the OTC shelf with no security enclosure, in a box that had to be carried to the register to be unlocked, or in a fixed locked case in the aisle. A self-selected subset of data collectors approached the pharmacy counter to ask whether there was an age restriction on the non-prescription sale of LNG EC, whether men could buy it, and whether EC customers needed to show identification. Those who asked questions at the pharmacy counter noted the job title of the person with whom they were speaking (pharmacist, pharmacy technician, manager, cashier, don’t know, or other). Data collectors also recorded descriptive information about each store, including store name, location (city and state), and area type (urban, suburban or rural, as determined by each data collector), as well as a subjective rating of how easy or difficult it was to locate EC in the store.

We used Chi-square analysis and Fisher’s exact test to detect bivariate associations. To identify differences in means, we used t-tests and Wilcoxon rank-sum tests. We collected data using Google Forms (Mountain View, CA) and conducted our analyses using Stata/SE

13.1 (College Station, TX). The Princeton University Institutional Review Board determined this study to be non-human subjects research.

Results

Forty-seven data collectors recorded information about 220 stores in 23 states. Half of these stores were located in the West, with about one-third in the Northeast and less than 10% each in the South or Midwest (Table 1). Most of the stores (61%) were described (as determined independently by each data collector) as being in an urban area, with smaller proportions in suburban (32%) and rural (6%) areas. This sample included independent and chain pharmacies (74%), grocery stores (14%), and big-box retailers (12%). Most stores included were part of a chain; only 17% operated independently. The distribution of chain and independent stores was not significantly related to area type ($p=0.066$). Data collectors provided information about OTC shelf availability of EC for all 220 stores and asked store staff additional questions about age and gender restrictions and identification requirements at a sub-set of stores ($n=159$; 72%).

Nearly two-thirds of the stores in our sample stocked EC on an OTC shelf in some form (Table 2). Of these stores, the majority (68%) kept EC in a plastic box that customers had to carry to the register to have unlocked, and a small proportion kept the product in a fixed locked case in the store aisle (8%). Only 14% of all stores had EC directly on an OTC shelf without any security enclosure, and in a few stores there was a labeled space for EC on an OTC shelf, but it was out of stock (4%). Most stores (88%) that stocked EC on an OTC shelf displayed it in the family planning aisle near the condoms and pregnancy tests, and small proportions sold EC in the feminine care aisle near the tampons and sanitary pads (8%) or in front of the pharmacy counter (4%). One-third of stores did not sell EC on an OTC shelf; in 75% of these stores, EC was located behind the pharmacy counter or at the register, and in the remaining 25% (which constituted 8% of the entire sample), EC was not available at all.

There was no difference in whether stores stocked EC on an OTC shelf when analyzed by region of the country, but there was a significant difference by area type. A greater proportion of stores in suburban areas (79%) stocked EC on an OTC shelf compared with urban (59%) or rural (57%) areas ($p=0.014$). Chain stores were more likely than independent stores to stock EC on an OTC shelf: while the majority of chain stores stocked EC on an OTC shelf, only two independent pharmacies did (77% vs 5%; $p=0.000$). Although chain stores more consistently stocked EC on an OTC shelf, there was variation in stocking practices among stores within the same chain. Among the four retail chains for which the most data were collected, no chain had consistent EC stocking practices across all locations (Figure 1).

Some store personnel provided specific reasons for why EC is not stocked on OTC shelves. Several reported that EC is held behind-the-counter for theft prevention, because of the high cost of the product. As noted by one data collector:

“Apparently people have been stealing EC off the shelves so the shelves are empty with no sign telling people where they can access it. You have to ask the cashier or another staff person to get it for you.”

(Chain pharmacy, Washington DC)

In other stores, staff said that they don't carry EC due to ideological objections. As one data collector reported:

“Pharmacy tech said they don't believe in it. It ‘interferes with fertilization’.”

(Independent grocery store, Colorado)

Among the 159 stores for which we have information about age and gender restrictions and identification requirements, the majority of store staff who answered questions were pharmacists (47%) or pharmacy technicians (45%). Forty percent of data collectors were told that there was an age restriction for purchasing EC without a prescription. However, there was substantial variation in what staff reported the age limit to be. The reported age for OTC access ranged from 13 years to 18 years, with the majority stating that a customer had to be at least 17 or 18 years old to buy EC without a prescription (Figure 2). Representatives from five stores told our data collectors that there was an age restriction but did not know what the exact age was. Among pharmacists and pharmacy technicians, nearly identical proportions (43.2% of pharmacists and 43.7% of pharmacy technicians) incorrectly reported that there was an age restriction on the sale of LNG EC. The number of staff in other staff level categories was very small (13 individuals in total; 8%) but all of these staff correctly reported that there was no age restriction.

There was a significant association between the presence of an age restriction and whether EC was sold on an OTC shelf: only about one-quarter of stores that sold EC on an OTC shelf reported an age restriction on the purchase of LNG EC, compared with nearly two-thirds in stores where EC was sold only behind the counter (27% vs 64%; $p=0.000$). The presence of a reported age restriction did not vary by geographical region or area type, but independent stores were more likely to have an age restriction than chain stores (65% vs 35%; $p=0.007$). Again, there was within-chain variation as to whether or not individual retail locations reported an age restriction; while most chain stores did not have an age restriction, for all chains, at least one location reported that there was a minimum age for the non-prescription sale of EC (Figure 3). Representatives from nearly all of the sub-set of stores for which we have information (95%) correctly explained to our data collectors that men can purchase EC without a prescription.

The average price of the branded product (Plan B One-Step[®]) was \$49.64 (range=\$39.99-\$58.99), and the average price of generic one-dose EC was \$40.05 (range=\$28.00-\$65.00). The average price for the branded product was not significantly different for chain stores compared with independent stores (\$49.68 vs \$49.16; $p=0.476$), although the average price of generic EC products was significantly higher at independent stores than chain stores (\$42.80 vs \$39.88; $p=0.022$). Average price was not related to whether the store was in an urban area or whether EC was sold on an OTC shelf.

Data collectors' subjective assessment of how easy or difficult it was to locate EC in the store was significantly related to whether EC was sold on OTC shelves. In stores that stocked EC on an OTC shelf, 86% of data collectors reported that the medication was “somewhat” or “very” easy to locate in the store, while only 11% of those collecting data in

stores that did not stock EC on OTC shelves reported that it was easy to find ($p=0.000$). Many of those who found EC on an OTC shelf commented that this created a comfortable environment for obtaining the medication. As reported by one data collector:

“I feel that someone buying EC at this store would feel very comfortable because the EC is not locked up in any way and the individual can purchase the item discreetly.”

(Big box chain store, California)

In contrast, in 78% of the stores that did not stock EC on an OTC shelf, our data collectors reported that it was “somewhat” or “very” difficult to find ($p=0.000$). Data collectors also expressed concern that the lack of OTC shelf availability would pose a barrier to access. As exemplified by one individual:

“I believe buying EC may be uncomfortable because it is locked and the individual would have to ask an employee --- drawing ‘unwanted’ attention.”

(Chain pharmacy, Illinois)

Discussion

Although all LNG EC products are now approved for over-the-counter sale without age, gender or point-of-sale restrictions, the reality of access is far less straightforward. Our data collectors reported a range of reasons that stores did not stock LNG EC on OTC shelves. Stores that do not stock EC on OTC shelves may be managed by individuals who do not know that LNG EC is now an OTC product with no age or gender restrictions. In other cases, store personnel may be fully aware of the regulatory status of EC, but may still hold the product behind a pharmacy counter in the interest of theft prevention, due to the high cost of the product. Other stores may choose not to stock EC on OTC shelves due to moral objections. The majority of stores in our sample displayed EC on OTC shelves in some form, but most of them used security enclosures, which may themselves pose a barrier for customers. In open-ended responses, several data collectors noted the uncomfortable experience of asking store personnel to unlock security boxes.

The fact that chain stores were more likely to stock EC on OTC shelves than independent stores may reflect relatively consistent policies set at the corporate level; however, there was variability within every chain represented in our survey in how EC was displayed and whether store personnel reported that there was a minimum age for non-prescription sale of EC. This suggests that improved education of store staff and managers (at the corporate level and within individual stores) is needed. There was no difference between pharmacists and pharmacy technicians in whether they correctly reported that there was no age restriction on the sale of LNG EC (all staff in other job categories all provided correct information, although numbers were very small for each category), so it appears that educational efforts should be directed to all staff and at the corporate level, not only one category of staff. The fact that independent pharmacies were less likely to stock EC on OTC shelves may reflect additional characteristics of these stores, potentially including less ability to absorb product losses (and therefore a heightened concern about theft) and smaller physical size, resulting in less OTC shelf space.

Stores that stocked EC on OTC shelves were more likely than those that did not to correctly report that there is no age restriction on the sale of non-prescription LNG EC, which suggests that an information deficit may be responsible for at least some of the restrictive stocking practices that EC customers encounter. The high price of LNG EC most likely contributes to access barriers not only because many women cannot afford it, but also because stores result to using anti-theft devices (such as locked boxes) or stocking EC behind the counter, both of which may compromise the privacy and comfort of customers.

Limitations

This study has several limitations. The data were collected from a convenience sample that is not nationally representative; therefore, it may not precisely reflect the general EC sales practices of stores around the country. Given that this was a convenience sample, this study was not powered to detect differences in area type or store type. In addition, data collectors determined the store's area type without specific guidance criteria; it is possible that one individual may consider their area to be urban, while another might consider the same area to be suburban. An additional limitation may be that only a subset of data collectors (72%) approached the pharmacy counter to ask additional questions about whether age restrictions and identification checks are imposed by the store, so the subset of data reporting on age restrictions may not represent the entire sample. However, this is the only published report that the authors are aware of that assesses availability and accessibility in the current EC regulatory context, and, despite these limitations, this study provides useful insights into how stores sell and display EC and how individuals experience purchasing it.

Implications for Practice and/or Policy

At last, US regulatory policy around LNG EC reflects the large body of evidence showing that the product is safe for use in women of any age and exceeds all safety requirements for OTC sale. Yet, in practice, LNG EC is not universally available OTC due (in part) to misinformation and confusion about regulations. Because EC pills are more effective the sooner they are taken, it is of the utmost importance that women can access them as quickly and easily as possible. Stores can improve women's access to LNG EC by developing and enforcing uniform policies that ensure that EC is stocked on OTC shelves and that outdated age or gender restrictions or identification requirements are not imposed. Education of staff, from pharmacists to check-out clerks, is essential to ensuring full OTC access to LNG EC as allowed by current FDA regulations. State Boards of Pharmacy can play a role in updating members on current regulations governing the sale of EC, and pharmaceutical companies should dedicate resources to educating retailers about the status of EC. In addition, public education about the regulatory status of LNG EC and inclusion of this information in sexuality education curricula may help create an environment of improved access.

Conclusions

Years of changes to the regulatory status of LNG EC have resulted in widespread confusion and misinformation about how it can be sold, and the result is substantial variation in the accessibility of the product. The high price of LNG EC combined with significant

misunderstanding of current regulations contributes to access barriers, and store practices continue to lag behind regulations. In order for women to access EC as soon as possible after unprotected sex, retail stores and pharmacies that sell EC should ensure that the product is available on OTC shelves and without age or point-of-sale restrictions. Consumers can exert pressure on retailers to comply with FDA regulations on the sale of LNG EC; the American Society for Emergency Contraception, in cooperation with the Reproductive Health Technologies Project and the American College of Clinical Pharmacy Women's Health Practice and Research Network, produces a guide for pharmacies detailing EC regulations and encourages consumers to show the guide to pharmacy staff if they encounter a problem purchasing EC (American Society for Emergency Contraception, 2016). When women need EC, time is of the essence and barriers must be removed.

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Figure 1.
Variations in Shelf Display of EC by Chain Pharmacy (n=133)

Figure 2.
Reported Age Restrictions on Non-Prescription Sale of LNG EC, Stratified by Store Stocking Practices

Figure 3.
Variations in Age Restrictions for Purchasing EC by Pharmacy Chain (n=104)

Table 1

Characteristics of Stores Surveyed (N=220)

Variable	Respondents n (%)
Store Type	
Chain	183 (83.2)
Independent	37 (16.8)
Store Category	
Pharmacy	163 (74.1)
Grocery	31 (14.1)
Big Box	26 (11.8)
Region	
Northeast	80 (36.4)
South	16 (7.3)
Midwest	13 (5.9)
West	111 (50.5)
Area	
Urban	135 (61.6)
Suburban	70 (32.0)
Rural	14 (6.4)
Title of staff responding to questions *	
Pharmacist	74 (46.8)
Pharmacy technician	71 (44.9)
Manager	1 (0.6)
Cashier	7 (2.5)
I don't know/other	5 (3.1)

* Among observations at the pharmacy counter; n=159

Table 2

EC Stocking and Sales Practices in Stores Surveyed (N=220)

EC Stocking and Sales Characteristics	n (%)
EC stocked on shelf	142 (64.5)
On shelf in plastic box	90 (40.9)
On shelf, not locked	31 (14.1)
On shelf in fixed locked case	12 (5.5)
Space on shelf but out of stock	9 (4.1)
EC not stocked on shelf	78 (35.5)
Behind pharmacy counter *	55 (25.0)
At cash register	4 (1.8)
Not available at all	18 (8.2)
Age restriction reported **	63 (39.6)

* Includes responses "In manager's office" (n=1) and "Behind cosmetics counter" (n=1)

** Question asked of a subset of stores; N=159