

January 2018

Not There Yet: ASEC's 2017 EC Access Study

Background and Summary

ASEC has tracked the accessibility of levonorgestrel emergency contraception (LNG EC) since the first approval for over-the-counter (OTC) sale in 2013. More than four years after the US Food and Drug Administration approved Plan B One-Step® for OTC sale, EC availability on the shelf is far from universal. On the positive side, anti-theft measures are in place less frequently, and a majority of respondents in 2017 again reported that it was somewhat or very easy to locate EC in the store. However, the price of EC has not changed since 2014, and misinformation about age restrictions and ID requirements continues to be presented to consumers. Both of these pose important barriers to access.

Findings in Brief

- A majority of the stores in this sample (60%) stock EC on the shelf (vs 65% in 2015)
- Among stores that stock EC on the shelf, 57% lock the product in a case or box that must be unlocked by a store employee (vs 71% in 2015)
- For 62% of participants, finding EC in the store was somewhat/very easy (vs 67% in 2015)
- 30% of stores impose an age restriction to purchase EC (vs 39% in 2017)
- The average price of Plan B One-Step® is \$49 and generics cost about \$39 (little change since 2014)
- Nearly all participants (98%) were told that men can purchase EC
- Independent pharmacies are far less likely to stock EC on the shelf and far more likely to impose an age restriction than chain pharmacies.
- Full OTC access is still not a reality

Introduction

"There was **one pill left in the whole store**. The aisles were small, and we looked over and over before asking someone at the pharmacy, who finally showed us the spot where they should be. I asked when they would be back in stock, and she had no idea. I would imagine if you really needed EC, it would be **really frustrating and stressful** to find it here, if they even have it available."

- Chain pharmacy in Wilsonville, OR

In 2013, the US Food and Drug Administration (FDA) approved the branded one-dose levonorgestrel emergency contraception (LNG EC) product, Plan B One-Step®, for sale directly on the shelf to women and men of any age with no point-of-sale restrictions. The following year, generic LNG EC products were approved for OTC sale, although with a confusing caveat: generic LNG EC packages (other than those sold by Teva Pharmaceuticals, the owner of the branded product) were required to list a use recommendation ("For women 17 years of age and older") that may have been interpreted as an enforceable restriction. The minimum age for OTC sale has changed several times; ongoing confusion and misinformation about the regulatory status of LNG EC, coupled with high cost, have led to great variations in individuals' access to the product. ASEC has tracked real-world access to EC since 2014 and found that, for many, true OTC access is still not a reality.

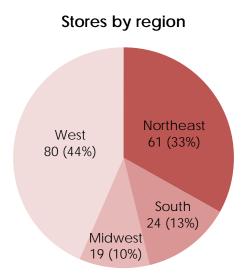
Methods

To conduct our third survey of EC access in retail locations across the United States (read our 2014 and 2015 reports), ASEC distributed an online survey via our listserv and through partner organizations from June to November 2017. Respondents visited local stores in person and described how EC was being sold in that store using a standardized questionnaire. All responses (184 stores) included in this report provided information about shelf availability of EC; a subset of participants (137 stores; 74%) asked pharmacy staff additional questions about age and gender restrictions and ID requirements. In this report, sale "on the shelf" included any type of packaging or box, even locked cases, as long as the product was in view in the aisle and not sold exclusively behind a pharmacy or cashier's counter.

Results

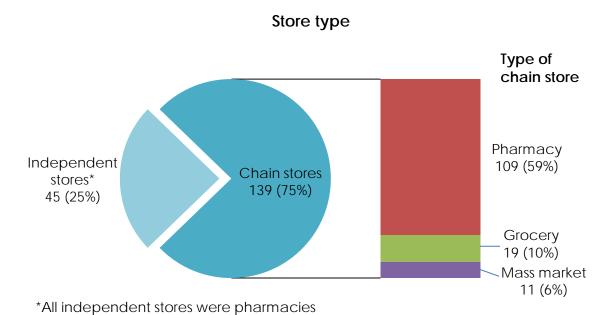
Geographical Distribution

Our sample includes 184 stores in 26 states. Nearly 45% of our sample is located in the West, with about one-third in the Northeast. About half (49%) of the stores were described as being in a suburban area, with 42% in urban and 9% in rural areas.



Store Type

This sample includes independent and chain pharmacies, grocery stores, and mass-market stores, such as Target. Pharmacies make up 84% of the sample, and 75% of all stores are part of a larger chain.



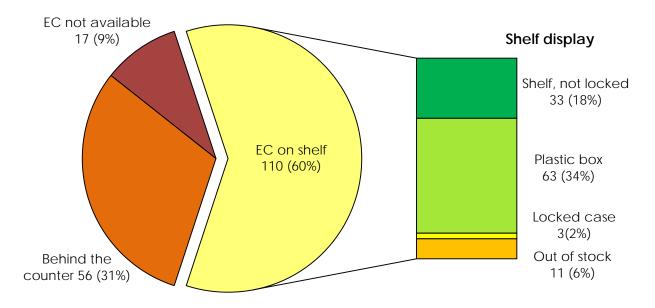
EC on the Shelf

"For me today it was relatively easy, but I know there are some days when they're out of stock on the shelf and the customer could feel uncomfortable asking about it. Additionally the overstock is kept in the pharmacy so if it is out of stock and outside of pharmacy hours...it would be impossible for the front store staff to retrieve more for a customer."

-Chain store in Cayce, SC

Sixty percent (n=110) of the stores surveyed had EC on the shelf in some form. Of these stores, the majority (57%, n=63) kept EC in a plastic box that customers had to carry to the register to have unlocked and 2% stored the product in a fixed locked case in the store aisle. Nearly one-third (30%, n=33) of all stores had EC directly on the shelf without any security enclosure, and 10% of stores had a space for EC on the shelf, but the product was out of stock. Forty percent (n=73) of stores did not sell EC on the shelf; in 77% of those cases, EC was located behind the pharmacy counter. But in 9% (n=17) of stores surveyed, EC was not available at all.

Availability and display of EC



Stores stocking EC on the shelf generally kept it in the family planning aisle near the condoms and pregnancy tests (76%, n=84). A smaller proportion (16%) of stores sold EC in the feminine care aisle near tampons and pads. In two stores, EC was stocked in the makeup aisle.

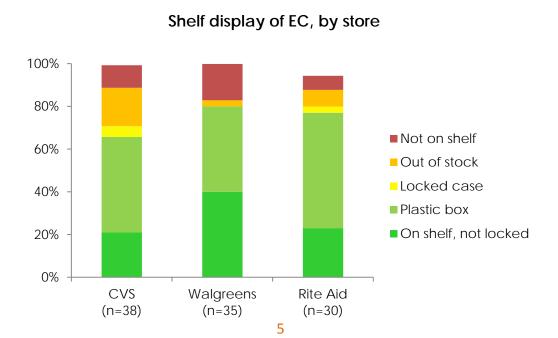
EC Shelf Availability

There was no difference in whether stores stocked EC on the shelf by region or neighborhood type. EC was significantly more likely to be stocked on the shelf in chain stores (76%) than independent stores (9%).



Variations in Stocking Practices by Store

Among and within the three pharmacy chains for which there were the most data (CVS, Rite Aid, and Walgreens), we found a lack of consistency as to how EC is being sold. For example, more than half of Rite Aid locations stocked EC in a plastic box on the shelf, while Walgreens locations were equally likely to stock EC unlocked on the shelf or in a plastic box.

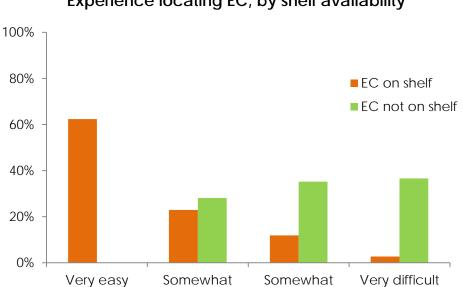


Locating EC in the Store

"Really difficult to find. You HAVE to ask for it. Pharmacist is behind a counter partitioned all around by glass."

-Independent pharmacy in Los Angeles, CA

We asked respondents how easy or difficult it was to locate EC. Not surprisingly, in stores that did not stock EC on the shelf, 72% of respondents reported that it was somewhat or very difficult to locate it. Conversely, among those who did find EC on the shelf, 85% reported that it was somewhat or very easy to locate.



Experience locating EC, by shelf availability

Finding EC available on the shelf, coupled with compassionate and knowledgeable customer service from a pharmacist, resulted in an excellent experience for this participant:

easy

difficult

"It was very easy to find and when I talked to the pharmacist she was very kind and gave me all the information I asked for and then some. She thought I was in need of it and she led me to where they were on the shelf and she explained to me how it worked and everything. I feel like not everyone's experience would be this pleasant because this woman was an angel but it was still not invasive in any way."

-Chain grocery store in Bloomington, IN

Age Restrictions

Among the 137 (74% of total) participants who approached the pharmacy counter to ask questions about restrictions, 30% (n=39) were incorrectly told that there is an age restriction for purchasing EC. The most common age minimum reported was 18 (n=28, 82%), and the remainder reported the minimum age as 17, and in one case, 21.

Until April 2016, generic EC packages not sold by Teva were required to list a "use recommendation" stating that the product was intended for use by women aged 17 and older. In our 2017 survey, only 7 (6% of those reporting) individuals found this old packaging on store shelves.

There was not a difference in age restrictions on the purchase of LNG EC by region of the country or neighborhood type. However, independent stores (67%) were significantly more likely to impose an age restriction than chain stores (18%). Compared to our 2015 data, there was greater consistency among chain stores as to whether an age restriction was imposed; in 2017, between 9% and 14% of individual stores within the most common chains imposed an age restriction, compared with a range of 13% to 39% in 2015.



Several participants reported disagreement between store personnel about age restrictions:

"Pharmacist said **21 and ID required**; Pharmacy tech said **18 and ID required**."
-Independent pharmacy, Concordia KS

Others were given vague and inconsistent guidance about whether ID is required:

"No [there isn't an age restriction], but it is company policy to check your ID since it is held behind the counter. This troubled me so I called back later and asked why and he said it was just a routine thing and that if someone didn't have an ID they would probably sell it to them anyway."

-Independent pharmacy, Bloomington IN

Gender Restrictions

Almost all (98.5%) stores asked correctly reported that men can buy EC. Two individuals were told that men can only buy EC if they have a woman with them or are in possession of a woman's ID; these appeared to be related to the misinformation that there is an age restriction on the sale of EC.

"Men can buy but **girlfriend must be with them** because need identification."
- Independent pharmacy in Los Angeles, CA

Average Price of EC

Across all 184 stores, the average price of Plan B One-Step® was \$49.48 and the average price of generic one-dose EC was \$38.74. Average prices for the branded product were higher at chain stores (\$49.67) compared with independent stores (\$47.56), but prices for generic products did not differ significantly.

The introduction of the My Way 2-pack (2 doses of 1.5mg LNG EC) is a recent development that could have a longer-term impact on price. The average price of this product across stores was \$59.81, and the per-dose cost (on average, \$29.91) is substantially lower than the average cost of any other EC product available in stores. This may be particularly useful for women interested in taking a double dose of LNG EC (those who weigh more than 154 pounds or are using certain enzyme inducers) or those stocking EC for future use.

Price is directly linked to access because many women simply cannot afford to pay \$40 or \$50. But participant comments highlight another connection between price and access: the price of EC creates a concern about theft, which is a common reason that store managers give for not stocking EC on the shelf:

"Pharmacist very nice- even gave me instructions for how to take pill. Said EC is a hot theft item so he kept it behind counter."

-Independent pharmacy, Buffalo WY

Is This Progress?

When we compare our 2017 findings to previous ASEC reports, we see that in some areas progress is being made. However, in others there is significant work to do.

What has improved?

- Anti-theft measures: Among stores that stocked EC on the shelf, 57% of stores in 2017 kept EC in a plastic locked box, compared to 63% of stores in 2015. For all years, a small proportion of stores kept EC in a locked case in the store aisle.
- Age restrictions: Misinformation about age restrictions continues to proliferate, although fewer respondents in 2017 (30%) were told that there is an age restriction than in 2015 (39%).
- Gender restrictions: Only two individuals (3%) were told that men cannot purchase EC without the presence or ID of a woman, compared with 8% in 2015.
- Chain pharmacies: A majority of chain stores are stocking EC on the shelf and following FDA guidelines that there is no age restriction or ID requirement for the purchase of LNG EC.

Where is more change needed?

- EC on the Shelf: In 2017, slightly fewer stores (60%) stocked EC on shelf than in 2015 (64%).
- Ease of Locating EC in the Store: Slightly fewer respondents in 2017 (62%) compared with 2015 (67%) reported that it was somewhat or very easy to locate EC in the store.
- Price: EC prices have not changed since our first report in 2014, despite the introduction of several generics to the market. Plan B One-Step® costs almost \$50 and generics are only about \$10 less on average. Price is still likely a major barrier to access for many women.
- Independent pharmacies: The majority of independent pharmacies still imposed age restrictions (68%) and don't stock EC on the shelf (91%).

At a Glance: Comparison of findings from 2014 to 2017

	2017	2015	2014
EC not available at all	9%	8%	*
EC on shelf	60%	65%	49%
Anti-theft measures**			
Plastic locked box	57%	63%	50%
Locked case in aisle	3%	8%	7%
Very/somewhat easy to locate EC	62%	67%	50%
Price	Brand: \$49 Generic: \$39	Brand: \$49 Generic: \$40	Brand: \$48 Generic: \$41
Age restriction	30%	39%	Yes*
Gender restriction	2%	5%	*

^{*}Not measured consistently in 2014

Conclusions

The regulatory changes that have taken place over the past several years around the sale of LNG EC are still confusing to retailers and consumers. Although OTC approval should have substantially improved access, consumers still face important barriers to purchasing EC, including inconsistent availability on the shelf, high cost, and misinformation around age restrictions and ID requirements. While access appears to be improving, substantial barriers remain. In addition to findings from this survey, ASEC continues to receive complaints from individuals across the country about barriers to accessing EC and refusals from store personnel to provide EC.

EC labels are no longer required to list a minimum user age. Understanding of the unrestricted OTC status of LNG EC appears to be improving, as a smaller proportion of participants in 2017 (30%) were told that there is an age restriction on the sale of EC than in 2015 (39%). However, this change is slow, particularly among independent stores, where 67% of participants were told that there is an age restriction. EC sales practices among chain stores are improving, but consistency can and should be further improved; given the centralized nature of chain drug stores, there is no reason that practices should vary by individual store. Policies that are consistent with FDA regulations and with the best interests of customers must be developed

^{**}Among stores where EC is sold on the shelf

and communicated to all store personnel. Education for pharmacy staff about EC is clearly needed.

The high price of EC remains a persistent problem. Not only does this create a direct barrier for women who can't afford EC, but pharmacy staff report that the cost (and related perceived risk of theft) is a major reason that EC is not stocked on the shelf. Trusted online retailers sell LNG EC at a reduced cost (such as afterpill.com) and priktruby.com), but because they do not offer expedited shipping, this is not a solution for women who need EC immediately. Clinics often offer EC at lower prices, and women for whom price is a major concern might consider obtaining EC from a Planned Parenthood or another community clinic. However, this may be a less accessible and convenient option, particularly for those who live in rural areas with fewer options.

While ASEC continues to monitor access to EC, we encourage colleagues and consumers to look for EC in stores and pharmacies and share your findings with us. When EC is not available on the shelf, ask store managers why that is and ensure that they understand that current regulations allow EC to be sold on the shelf with no restrictions; our <u>Guide for Pharmacies and Retailers</u> is a useful tool for educating store personnel on the often-confusing landscape of EC regulations.

EC pills are more effective the sooner they are taken, so any barrier that creates a delay in access can increase the risk of pregnancy. It has been four years since the first OTC approval for LNG EC; it's time for true OTC access for everyone.