

Emergency contraception: Update for pharmacists

Linda Dominguez, Donald F. Downing, Beth Jordan, Deborah Kurnik, Eleanor B. Schwarz, James Trussell, and Elizabeth Westley

Abstract

Objective: To provide pharmacists with updated information on emergency contraception (EC).

Data sources: Searches of PubMed were conducted using one or more of the following terms: *emergency contraception, EC, Next Choice, Plan B One-Step, unintended pregnancy, morning-after pill, and pharmacists*. References and related articles from relevant articles were searched to retrieve additional articles. In addition, Google was used to identify national organizations that are dedicated to EC, and the websites of these organizations were searched for additional information.

Data extraction: By the authors.

Data synthesis: About one-half of the 6-million pregnancies per year in the United States are unintended. EC has the potential to reduce a woman's risk of unintended pregnancy. Pharmacists have become a critical link between EC and the women who need it. In the previous decade, the regulatory status for EC drugs has shifted from prescription only to OTC for those 18 years of age or older and now to OTC for those 17 years or older. Although the changes and dual status have improved access to EC, they have also created confusion among patients, clinicians, and pharmacists.

Conclusion: EC is a safe and effective method of preventing unintended pregnancy after unprotected intercourse. Pharmacists are in a unique position to assist patients in need of EC. As frontline providers, they have the opportunity to offer support on many levels, including counseling individual patients, helping inform the community about EC, and becoming advocates for improved access to EC for low-income women and those younger than 17 years of age.

Keywords: Emergency contraception, unintended pregnancy, morning-after pill, risk taking, barriers to access, over the counter.

Pharmacy Today. 2010(Jun);50(6):48-60.

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Acknowledgments: To Dr. Trussell and Elizabeth G. Raymond, MD, MPH, Associate Medical Director, Family Health International, for developing considerable original content.

The American Pharmacists Association and the Association of Reproductive Health Professionals have collaborated for the purpose of developing and providing this continuing pharmacy education activity.



Accreditation Information

Provider: American Pharmacists Association

Target audience: Pharmacists

Release date: June 1, 2010

Expiration date: June 1, 2013

Fee: There is no fee associated with this activity for members of the American Pharmacists Association. There is a \$15 fee for nonmembers.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of CPE. The ACPE Universal Activity Number assigned to the program by the accredited provider is 202-999-10-148-H01-P.

Disclosure: Ms. Dominguez has received an honorarium for serving as a consultant and speaker for Teva/Barr, Wyeth, and Schering Plough. The other authors, Association of Reproductive Health Professionals staff, and APhA's editorial staff declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, or honoraria.

Funding: This activity is supported by an educational grant from Duramed Research, Inc., a subsidiary of Teva Pharmaceuticals.

ACPE number: 202-999-10-148-H01-P

CPE credit hours: 2.0 hours (0.2 CEUs)

ACPE activity type: Knowledge-based

Learning objectives

At the completion of this activity, the pharmacist will be able to:

Describe progestin-only emergency contraception (EC) products, regimens, and access issues to ensure more consistent usage by patients.

Outline and discuss mechanism of action of EC with patients as a means of dispelling myths surrounding these products.

Respond to patients' concerns about the safety and efficacy of EC products using FDA guidelines.

Provide evidence-based EC information and appropriate counseling and care to patients to ensure improved patient health care outcomes.

Unintended pregnancy continues to be a major public health issue in the United States. About one-half of the 6-million pregnancies in the United States each year are unintended.¹ The majority of women in their child-bearing years (15–44 years of age) use some form of contraception, but more than one-half of all unintended pregnancies occur when these women experience contraceptive failure. The remaining pregnancies occur in women not using any contraceptive method.² Therefore, efforts to increase use of contraceptives for those experiencing method failure or those not using any method could potentially decrease the rate of unintended pregnancy (Figure 1).

Emergency contraception (EC) has the potential to reduce women's risk of unintended pregnancy, and EC medications are the only contraceptive method that can easily be used postcoitally to prevent pregnancy.³ EC is a therapy for women who have had unprotected sexual intercourse, including sexual assault and known or suspected contraceptive failure, and want to avoid pregnancy. The two most common reasons for seeking EC are failure of a barrier method (usually condoms) and failure to use any contraceptive method.⁴

At a Glance

Synopsis: PubMed and other sources were searched to provide pharmacists with updated information on emergency contraception (EC). Approximately 50% of the 6-million pregnancies per year in the United States are unintended, and EC has the potential to reduce the risk of unintended pregnancy. Although regulatory changes and dual status (prescription only or OTC based on age) have improved access to EC, they have also created confusion among patients, clinicians, and pharmacists. As frontline providers, pharmacists are uniquely positioned to assist patients with EC, including counseling individual patients, helping inform the community about EC, and becoming advocates for improved access to EC for low-income women and those younger than 17 years of age.

Analysis: Evidence has shown that unless ECPs are used more frequently and when needed, a major public health impact will not be realized. Because direct-to-patient advertising for ECPs is scarce, many women do not know that ECPs are effective, safe, and readily available in pharmacies. Lack of information from health care providers further limits awareness and knowledge of EC and its availability; in a 2002 survey, only 3% of women reported discussing EC with a health care provider in the previous year. Although EC has not reduced unintended pregnancy at the population level, predictions by EC opponents that easier access to OTC EC would lead women to have more unprotected sex and more abortions have been unrealized as well.

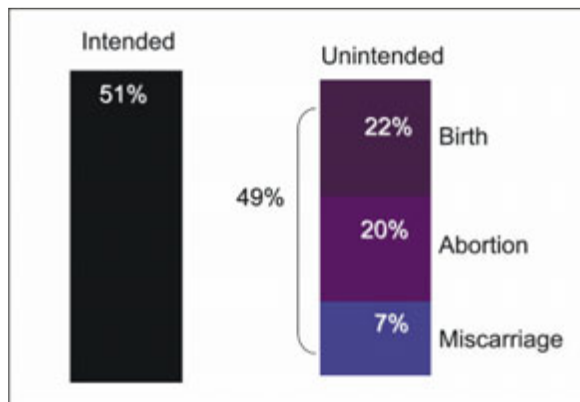


Figure 1. Annual pattern of pregnancies in the United States: Intended versus unintended pregnancies (6.3 million pregnancies total)

Source: Reference 1.

Even women who do not desire pregnancy may practice contraception poorly or not use a birth control method. This contradiction can be explained by a number of factors, including women's ambivalence about potential pregnancy; experiences with contraceptive methods; partner influences; lifestyle factors such as travel, work, and relationships; and interactions with contraceptive care providers. These factors influence gaps in contraceptive use, which heighten the risk of unintended pregnancy.⁵

The need for EC and ready access to it may be more critical when women and families are faced with financial hardship. In the best of economic times, the poorest women are more likely to face unintended pregnancy. The Guttmacher Institute recently collected data on the effect of recession on women's family-planning decisions. In the current recession environment of increasing unemployment, lower incomes, and concerns about health insurance and access to care, one in four women have delayed a gynecologic or birth control visit to save money and one in four women are having a harder time paying for birth control. Many are stretching their monthly medication supply, changing to a less expensive (and perhaps less effective) method, or not using a contraceptive.⁶

EC products (ECPs) are available without a prescription behind pharmacy counters for purchase by women and men 17 years of age or older in the United States. In the previous decade, the regulatory status for ECPs has evolved from prescription only to OTC for those 18 years or older and now to OTC for those 17 years or older. Although the changes and dual status (prescription only or OTC based on age) have certainly improved access to EC, they have also created confusion among patients, clinicians, and pharmacists.

EC methods

Emergency contraceptives available in the United States include ECPs and the Copper T intrauterine device.^{4,7,8} This article will cover information about ECPs.

Table 1. Oral contraceptives approved for EC in the United States

Brand	Manufacturer	Tablets per dose ^a	Ethinyl estradiol per dose (µg)	Levonorgestrel per dose (mg) ^b
Progestin-only dedicated EC (take one dose)^c				
Plan B One-Step	Teva	1 white tablet	0	1.5
Next Choice	Watson	2 peach tablets	0	1.5
Combined progestin and estrogen tablets (take two doses 12 hours apart)				
Aviane	Teva	5 orange tablets	100	0.50
Cryselle	Teva	4 white tablets	120	0.60
Enpresse	Teva	4 orange tablets	120	0.50
Jolessa	Teva	4 pink tablets	120	0.60
Lessina	Teva	5 pink tablets	100	0.50
Levora	Watson	4 white tablets	120	0.60
Lo/Ovral	Akrimax	4 white tablets	120	0.60
LoSeasonique	Teva	5 orange tablets	100	0.50
Low-Ogestrel	Watson	4 white tablets	120	0.60
Lutera	Watson	5 white tablets	100	0.50
Lybrel	Wyeth	6 yellow tablets	120	0.54
Nordette	Teva	4 light-orange tablets	120	0.60
Ogestrel	Watson	2 white tablets	100	0.50
Portia	Teva	4 pink tablets	120	0.60
Quasense	Watson	4 white tablets	120	0.60
Seasonale	Teva	4 pink tablets	120	0.60
Seasonique	Teva	4 light blue-green tablets	120	0.60
Sronyx	Watson	5 white tablets	100	0.50
Trivora	Watson	4 pink tablets	120	0.50

Abbreviation used: EC, emergency contraception.

^aPlan B One-Step and Next Choice are the only dedicated products specifically marketed for EC in the United States. Aviane, Cryselle, Enpresse, Jolessa, Lessina, Levora, Lo/Ovral, LoSeasonique, Low-Ogestrel, Lutera, Lybrel, Nordette, Ogestrel, Portia, Quasense, Seasonale, Seasonique, Sronyx, and Trivora have been declared safe and effective for use as EC products (ECPs) by FDA. Outside the United States, more than 100 ECPs are specifically packaged, labeled, and marketed. Levonorgestrel-only ECPs are available either OTC or from a pharmacist without having to see a clinician in 60 countries. Plan B One-Step and Next Choice are available OTC to women and men 17 years or older in the United States.

^bThe label for Plan B One-Step indicates taking the tablet within 72 hours after unprotected intercourse. Research has shown that all brands listed here are effective when used within 120 hours after unprotected sex. The label for Next Choice directs to take one tablet within 72 hours after unprotected intercourse and another tablet 12 hours later. Research has shown that that both tablets can be taken at the same time with no decrease in efficacy or increase in adverse effects and that they are effective when used within 120 hours after unprotected sex.

^cThe progestin in Cryselle, Lo/Ovral, Low-Ogestrel, and Ogestrel is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each tablet is twice the amount of levonorgestrel.

Source: Reference 9.

ECPs

Table 1 shows the two types of ECPs that are available in the United States: combined ECPs containing both estrogen and progestin (Yuzpe method) and progestin-only ECPs.

Combined ECPs contain the hormones estrogen and progestin. The specific agents that have been studied extensively in clinical trials of ECPs are the estrogen ethinyl estradiol and the progestins levonorgestrel and norgestrel. A specially packaged combined ECP (Preven Barr Laboratories) was approved by FDA in 1998 but withdrawn from the market in 2004 based on data showing that progestin-only EC was more effective. Combining estrogen and progestin hormones in this manner is also called the Yuzpe method, after the Canadian physician who first described the regimen.

Progestin-only ECPs have largely replaced combined

ECPs because they are more effective and cause fewer adverse effects. Although ECPs are commonly known as morning-after pills, the term is misleading; ECPs may be initiated sooner than the name implies or much later than the morning after. ECPs are most effective when taken immediately after unprotected intercourse. Efficacy declines as time elapses between sex and drug administration. ECPs are approved by FDA for use up to 72 hours after intercourse. They are reasonably effective for up to 120 hours and perhaps longer.⁹ However, patients should remember that progestin-only ECPs are more effective the sooner they are taken after unprotected sex.¹⁰⁻¹³

The products currently approved by FDA for use in the United States contain the progestin levonorgestrel. Two progestin-only products are currently available in the United States:

Next Choice (Watson; two 0.75-mg tablets), approved

by FDA in June 2009, is the branded generic of its two-tablet predecessor, Plan B (Duramed; first approved by FDA in July 1999).

Plan B One-Step (Duramed; single 1.5-mg tablet), approved by FDA in July 2009.

The original treatment schedule was one 0.75-mg dose within 72 hours after unprotected intercourse and a second 0.75-mg dose 12 hours later. The 72-hour marker is listed on the label for both of the currently marketed ECPs. However, subsequent studies have shown that a single 1.5-mg dose is as effective as two 0.75-mg doses 12 hours apart.^{10,11} A single 1.5-mg dose is now considered the evidence-based standard, and it can be effective up to 120 hours after unprotected intercourse. This dosing regimen is easier for women and enhances adherence.

When ECPs specifically indicated for EC are not available, certain other oral contraceptives can be used in specified combinations for EC. The regimen is one dose followed by a second dose 12 hours later, where each dose consists of up to six tablets, depending on the brand. Currently, 19 brands of combined oral contraceptives are approved in the United States for use as EC.

Effectiveness

The published literature on progestin-only EC (Next Choice and Plan B One-Step) estimates a range of effectiveness between 52% and 94% in reducing pregnancy risk based on nine studies of nearly 10,500 women.^{10-12,14-19} The effectiveness listed on the Plan B One-Step package is 89%. Data clearly show that the progestin-only EC regimen is more effective than the Yuzpe method. Both Yuzpe and progestin-only regimens are more effective than using no method of contraception.²⁰

The published literature on combined progestin-estrogen EC estimates a range of effectiveness between 56% and 89% in reducing pregnancy risk. A meta-analysis of eight studies concluded that the effectiveness of the combined regimen is 74%.²¹

Most published efficacy data likely overestimate the effectiveness of ECPs. For EC, efficacy was demonstrated initially in noncomparative observational studies; thereafter, use of a placebo was believed to be unethical. Therefore, the chance that pregnancy would occur in the absence of EC is estimated indirectly using published data on the probability of pregnancy on each day of the menstrual cycle.^{22,23} This estimate is compared with the actual number of pregnancies observed after treatment in observational treatment trials. Effectiveness is calculated as $1 - (O/E)$, where O and E are the observed and expected number of pregnancies, respectively.⁹

Calculation of effectiveness involves many assumptions that are difficult to validate. Accurate estimates of efficacy depend on accurate recording of timing of intercourse and cycle day (to estimate timing of ovulation).⁹ One study comparing self-report of cycle day with urinary pregnanediol concentrations demonstrated that more than

Case study 1

Woman who has missed oral contraceptive doses

A woman comes to the pharmacy counter and tells you that she has missed the first three doses of her birth control medication and wonders if she needs emergency contraception (EC).

Ask the woman if she has a few moments to talk privately.

Ask her whether she has had unprotected sex within the previous 120 hours. If she has, offer to provide her with EC products. If she has had sex without using a condom, you might inform her to consider a follow-up visit with her primary provider for an examination for sexually transmitted diseases.

If she has insurance coverage and you practice in one of nine states that allow pharmacist-initiated prescription of EC, you can prescribe EC and generate an insurance claim.

If the woman has time, ask her if she's satisfied with her current form of ongoing contraception and if she commonly misses doses. Suggest other forms of ongoing contraception, provide her with information about other methods, and make a referral if needed.

30% of women presenting for ECPs had inaccurately dated their menstrual cycles, believing themselves to be in the fertile phase of their cycle when they were not. In the same study, 60% reported more than one act of intercourse in the cycle, indicating that pregnancies attributed to ECP failure might actually be the result of unprotected intercourse earlier in the cycle.²⁴ Another study found that 99 women were between days -5 and +1 when the day of ovulation (day 0) was estimated as usual cycle length minus 13 days. However, hormonal data indicated that only 51 of these 99 (56%) were between days -5 and +1.²⁵ In another study, cervical smears showed that more than one-third of women requesting ECPs had no sperm present in the vagina and that those with sperm present had fewer sperm than women attempting to become pregnant.²⁶ For a variety of reasons, many women do not accurately understand when they are at risk for pregnancy.

The efficacy of progestin-only EC may be enhanced by adding a nonsteroidal anti-inflammatory agent that is specific for a cyclooxygenase-2 (COX-2) inhibitor. A pilot study of 41 women found that adding a COX-2 inhibitor (meloxicam 15 mg) to levonorgestrel 1.5 mg significantly increased the proportion of cycles with no follicular rupture or ovulatory dysfunction (88% vs. 66%, $P = 0.012$). Adding a COX-2 inhibitor can disturb the ovulatory process after the onset of the luteinizing hormone surge.²⁷ Generic meloxicam is covered by many community pharmacy generic plans. A trial regarding optimal dosing is under way.

Mechanism of action

ECPs may theoretically prevent pregnancy through several mechanisms. The most likely mechanism of action is the inhibition or delay of ovulation.

Several clinical studies have shown that combined ECPs containing the estrogen ethinyl estradiol and the progestin levonorgestrel can inhibit or delay ovulation.²⁸⁻³¹ Although early studies indicated that alterations in the endometrium after treatment with the regimen might impair

Case study 2

Man wants to purchase EC for girlfriend

A man comes to the pharmacy counter and wants to know if you will sell him emergency contraception (EC) products for his girlfriend.

Tell him that you would be happy to provide him with EC if he is eligible.

Ask for his identification to verify that he is old enough (at least 17 years) to buy OTC EC.

If he is old enough, sell him the EC.

If he is not old enough but his girlfriend is, let him know that she can purchase the EC herself. Alternatively, someone else who is old enough to purchase EC without a prescription may purchase the products.

receptivity to implantation of a fertilized egg, more recent studies have found no such effects on the endometrium.^{32,33} Additional possible mechanisms include interference with corpus luteum function; thickening of the cervical mucus resulting in trapping of sperm; alterations in the tubal transport of sperm, egg, or embryo; and direct inhibition of fertilization.^{7,34-36} No clinical data exist regarding the last three possibilities.

Treatment with levonorgestrel-only ECPs as soon as possible after unprotected sex has been shown to impair the ovulatory process and luteal function. Levonorgestrel-only ECPs can inhibit ovulation but do not always do so, even when given before ovulation.³⁷⁻⁴² Inhibiting ovulation may be the only mechanism of action for levonorgestrel-only ECPs. Recent studies have found no effect on the endometrium.⁴²⁻⁴⁴ In one study, levonorgestrel 1.5 mg had no effect on the quality of cervical mucus or on the penetration of spermatozoa in the uterine cavity.⁴³

Animal studies demonstrated that levonorgestrel administered in doses that inhibited ovulation had no postfertilization effect that impaired fertility.^{36,45,46} Whether these results can be extrapolated to humans is unknown. Based on those animal studies and their own studies in women, Novikova et al.⁴⁷ argued that most, if not all, of the contraceptive effect of both combined and progestin-only ECPs can be explained by inhibited or dysfunctional ovulation. This question of postfertilization effect may never be answered unequivocally because no test exists for fertilization itself, only tests for pregnancy. Thus, although proving that ECPs have no postfertilization effect in humans is not possible, the best available evidence indicates that levonorgestrel does not interfere with any postfertilization events.

ECPs do not interrupt an established pregnancy, which medical authorities such as FDA, the National Institutes of Health,⁴⁸ and the American College of Obstetricians and Gynecologists⁴⁹ define as beginning with implantation. Based on these considerations, ECPs are not abortifacients.^{50,51}

Safety

Millions of women have used EC safely and effectively. The benefits of using ECPs outweigh the risks in all situations.⁵²

Almost every woman who needs ECPs can use them safely, even those with contraindications to the routine use of combined hormonal contraceptives. Women with previous ectopic pregnancy, cardiovascular disease, migraines, and liver disease may use ECPs. In fact, research has shown that pregnancy poses a greater threat to women with medical problems such as thromboembolic and liver disease than a 1-day dose of estrogen and/or progestin.⁵³

Women who are breastfeeding may safely use ECPs. They may experience a transient change in their milk supply.

No risk of serious harm for moderate repeat use of ECPs appears to exist, and repeated use of ECPs is safer than pregnancy.⁹ The risk of birth defects does not increase if pregnancies occur after use of ECPs. Postmarketing surveillance since 1999 has shown no increase in the risk of ectopic pregnancies and no reports of overdose, overuse, or abuse.⁵⁴

The safety of ECPs does not change with age; therefore, they carry no added risks for those younger than 17 years.⁵⁵

Possible ECP adverse effects include nausea and vomiting, abdominal pain, breast tenderness, headache, dizziness, and fatigue. These effects usually do not occur for more than a few days after treatment, and they generally resolve within 24 hours.⁹ Considerably fewer adverse effects occur with progestin-only ECPs compared with combination products. Combination ECPs can cause nausea in up to 50% of women and vomiting in up to 20%.^{12,56} Women may experience a shorter or longer menstrual cycle depending on when ECPs are taken.^{57,58}

Impact of EC on risk taking

One of the concerns expressed about making EC available OTC was that easy access would encourage women, particularly adolescents, to increase risky sexual behavior and reduce their routine use of regular methods of contraception. Reported evidence from studies conducted around the world demonstrated that making ECPs more widely available does not increase risk taking or adversely affect regular contraceptive use.⁵⁹⁻⁶⁹ In studies of ECP use and risk taking, women were randomized to receive either counseling and ECPs on demand or ECPs in advance for later use. Reanalysis of one of the randomized trials suggested that easier access to ECPs may have increased the frequency of unprotected coital acts.⁷⁰ Women in the increased-access group were significantly more likely to report that they had ever used EC because they did not want to use condoms or another contraceptive method.⁷¹

Impact of EC on unintended pregnancy: Population level

No published study has demonstrated that increasing access to ECPs reduces pregnancy or abortion rates at the population level,⁷²⁻⁷⁴ although one demonstration project⁷⁵ and three clinical trials^{68,69,73} were specifically designed to

address this issue. One explanation for this result is that even when provided with ECPs in advance of need, most women use ECPs too rarely after risky incidents to result in a substantial population effect.

In a trial conducted in San Francisco, 45% of women in the advance-provision group who had unprotected intercourse during the study period did not use ECPs.⁶⁸ In a Chinese trial, 30 women in the advance-provision group (n = 746) did not use ECPs in the cycle in which they became pregnant.⁶⁹ In a Nevada/North Carolina trial, 33% of women in the advance-provision group had unprotected intercourse at least once without using ECPs and 57 did not use ECPs in the cycle in which they became pregnant.⁷³

In a demonstration project, 27 women with advance supplies of EC who became pregnant never used ECPs.⁷⁵ In a Nevada/North Carolina trial, increased access to EC had a greater impact on use of ECPs among women who were at lower baseline risk of pregnancy.⁷⁶ This may explain in part why increased access to EC has increased use of EC without measurable effect on pregnancy rates in clinical trials.

Thus, although considerable evidence shows that levonorgestrel ECPs are effective, several lessons can be learned from the lack of reduction in pregnancies. Women often underestimate their risk of pregnancy, and education is needed to encourage women to use ECPs every time they are needed. OTC access is necessary but probably will not reduce unintended pregnancies sufficiently. Unless ECPs are used more frequently and when needed, a major public health impact is unlikely.⁷²

Although the effect of EC on unintended pregnancy rates for the overall population remains to be shown, EC is most certainly of benefit to individual women seeking to prevent an unintended pregnancy after unprotected intercourse has occurred. Women who recognize their pregnancy risk are likely to seek EC if they are aware of it, and EC is easily accessible.

While the population effect promise of EC has been largely unrealized, so have predictions of disaster. Abortion opponents said easier access to Plan B would lead women to have more unprotected sex and more abortions. No evidence suggests that either outcome has occurred.

Barriers to EC access and use

Timely access to EC is essential. Access has improved considerably since FDA approved OTC status for progestin-only emergency contraceptives for anyone 17 years or older. However, barriers to EC access and use continue to exist and are brought about by politics, lack of awareness, lack of clinician discussion of EC and its availability, and other issues.

Political barriers

The fact that many emergency departments do not provide EC services to women who have been raped is a tragic example of neglected preventive health care.^{77,78} One 2005 survey found that 55% of Catholic and 42% of non-Catholic

U.S. hospitals did not dispense EC in emergency departments.⁷⁷ The Department of Justice makes no mention of EC in the 130-page *A National Protocol for Sexual Assault Medical Forensic Examinations* that was published in September 2004.^{79,80} Despite these obstacles, efforts are under way to reduce barriers to EC access in emergency departments. As of 2009, 15 states and the District of Columbia had laws requiring emergency departments to provide information about or access to EC to sexual assault survivors.⁸¹

Additionally, the Department of Defense Pharmacy & Therapeutics Committee removed the levonorgestrel ECP from the Basic Core Formulary (BCF; medications that must be stocked at every full-service Military Treatment Facility [MTF]) in May 2002, only 1 month after the drug had been added to the BCF,⁸² because of complaints from conservative members of Congress.⁸³ Whether the drug is stocked is left to the discretion of each MTF. Levonorgestrel ECPs were not available to all American soldiers serving overseas, which was of particular concern for women who were raped or faced an unintended pregnancy, until Next Choice was added to the BCF on February 3, 2010.⁸⁴

Lack of marketing and awareness

Direct-to-patient advertising for ECPs is scarce.⁹ Consequently, many women do not know that ECPs are effective, safe, and readily available in pharmacies.⁹

Lack of discussion with a health care provider

According to data from the 2002 National Survey of Family Growth, only 3% of women reported that a health care provider had discussed EC with them in the previous year.^{9,85} Lack of information from a trusted health care provider further limits women's awareness and knowledge of EC and its availability.

Other barriers

Access to EC remains limited for certain patient populations, such as female patients younger than 17 years, women with low income, and women without proper identification, including undocumented residents.^{57,86} Most Medicaid

Case study 3

Young female wants EC after she was raped

A young-looking female tells you that she needs emergency contraception (EC). She tells you that she's been raped and that she is 15 years old.

You can prescribe EC if you practice in one of nine states that allow pharmacist-initiated prescription of EC. If she doesn't have money to purchase EC, check your pharmacy's policy about "charity care" for these kinds of situations.

If you can, provide her with EC, then talk with her and coordinate a referral to a local Title X clinic/Planned Parenthood clinic or emergency department to provide her with posttrauma care. Consider having a pharmacy staff person escort the girl to the referral site.

If you are not able to directly provide her with EC, you should consider contacting a local Title X clinic/Planned Parenthood clinic or emergency department for EC and posttrauma care.

In most states, this situation would mandate a report to a child protection service.

beneficiaries and others seeking insurance coverage for EC still require a prescription. At an average retail price of about \$45, the cost of ECPs is prohibitive for many individuals, including college students. Health care providers can help women in these difficult situations by keeping a referral list of other family-planning clinics that use a sliding scale to determine charges for those who are low income or do not have insurance coverage. ECPs can often be obtained from these clinics for a reduced rate or for free.

OTC availability and regulatory status

Both Plan B One-Step and the generic Next Choice two-tablet product are approved by FDA for sale without a prescription to women and men aged 17 years or older in the United States. A government-issued identification is required for proof of age to purchase Plan B without a prescription.^{87,88}

Although most women can obtain progestin-only ECPs without a prescription, female patients aged 16 years or younger still need a prescription from a health care provider. The EC OTC status for patients 17 years or older and prescription-only status for female patients younger than 17 years or women without proper identification (so-called dual-label status of these products) necessitates keeping ECPs behind the counter in pharmacies. FDA wanted patients to have access to a knowledgeable health care provider who could answer questions patients might have when purchasing ECPs. Therefore, the products may be shipped to and stocked only by pharmacies or clinics and are not available at general retail locations that do not employ a licensed health care provider.

In pharmacy-access states, specially trained pharmacists can decide whether EC is medically appropriate for the woman requesting it and can prescribe ECPs to female patients of any age, including those who do not have government-issued identification for proof of age. Currently, the states with pharmacy access to EC are Alaska, California, Hawaii, New Hampshire, New Mexico, Massachusetts, Maine, Vermont, and Washington.⁸⁹

The American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and Society for Adolescent Medicine have all supported the availability and use of EC in teens.⁵⁷ Studies show that adolescents are capable of using ECPs correctly and safely and that access to EC is not associated with increased rates of unprotected intercourse, decreased use of condoms, or higher rates of pregnancy or sexually transmitted infections.^{57,90,91} If not in a pharmacy-access state, pharmacists can help female patients younger than 17 years obtain ECPs by offering a list of local clinicians and clinics that provide prescriptions for ECPs.

Access to ECPs for adult patients has been increased by their OTC availability. Pharmacies also lower access barriers by not requiring appointments; being open evenings, weekends, and holidays; and offering OTC EC to both women and men who meet the age requirement.

Table 2. Action items for pharmacists regarding EC

Stock and dispense EC.
Make sure all of your pharmacy's employees, particularly those who answer the telephones, know that you provide EC.
Routinely discuss EC with appropriate patients (e.g., new users of oral contraceptives, condom users).
Provide ECPs in advance to patients when possible.
Determine your state's requirements for prescribing ECPs to patients 16 years of age or younger.
In states with pharmacy access to EC, prescribe ECPs for female patients younger than 17 years.
In other states, suggest that patients younger than 17 years obtain a prescription from their health care provider for use if ECPs are needed.
Advertise the availability of EC in your pharmacy.
List your pharmacy in directories of pharmacies carrying EC.
Have an area available where you can discuss EC with patients confidentially.

Abbreviations used: EC, emergency contraception; ECP, emergency contraception product.

Of important note, patients seeking EC are not subject to the same requirements as patients seeking pseudoephedrine and other potential methamphetamine precursors; purchasers of EC do not need to sign a registry in the pharmacy, and no limits exist for the maximum quantity that can be purchased. Similar to the sale of OTC nicotine products, the sale of EC is limited only by the age of the purchaser, with no requirement for record keeping of purchases.

Pharmacist consultation

Because of their dual-label status, OTC ECPs are kept behind pharmacy counters. This placement provides pharmacists with an opportunity to play a crucial role in providing advice and information to patients about EC. OTC sale to patients 17 years of age or older improves access to EC by removing the delay associated with obtaining a prescription for this time-sensitive medication, thereby increasing use of this safe and reliable method for preventing an unplanned pregnancy. Pharmacists have become a critical link between EC and women who need it.

Dispensing and selling ECPs

Practices may vary by pharmacy and state; however, pharmacists are only required to verify the age of the OTC EC purchaser. If the individual is aged 17 years or older, the ECPs can be sold, and no other screening or counseling is required. If a woman has public or private insurance coverage of prescription EC, then pharmacists in pharmacy-access states can prescribe EC to ensure insurance coverage even though the woman is eligible for OTC EC based on her age. In some instances, counseling may be viewed as intrusive or an additional barrier to access to OTC EC. The pharmacist must determine whether such services are desired by the purchaser. Prescription EC counseling is mandated by federal and state laws.

If the patient is interested and has the time and the pharmacist has a private area in which to counsel, the pharmacist may provide the patient with a short summary of key issues, including ongoing contraceptive options, and offer further counseling. Pharmacists should be aware that some patients may feel stressed or embarrassed when inquiring about EC.

Additional considerations for pharmacists

Pharmacists may offer EC to appropriate patients (e.g., condom users, parenting teens, those taking oral contraceptives) in advance of need. Having EC on hand may help these individuals take it sooner after an incident of unprotected intercourse.

In pharmacy-access states, pharmacists provide patient assessment, consultation, and EC prescribing.⁹² Policies about paying pharmacists for this type of service vary among states and insurance companies.

As EC has evolved, pharmacists in many states have been actively engaged in making it available to more women (Table 2). In pharmacy-access states, this often has been achieved through the development of collaborative practice agreements permitting pharmacists to prescribe ECPs.⁹³ Experts in pharmacy provision of EC urge all pharmacists to join their colleagues in providing this important component of women's health care.

Conclusion

EC is a safe and effective method of preventing unintended pregnancy after unprotected intercourse. The EC environment has changed considerably during the previous decade with the regulatory status for ECPs in the United States shifting from prescription only to OTC for those 18 years of age or older and now to OTC for those 17 years or older. Two dedicated ECPs are now available without a prescription behind pharmacy counters for women and men 17 years or older in the United States.

Although the changes have improved access and removed some barriers to the use of EC, they have also created confusion for patients and health care providers. Health care providers play a crucial role in educating themselves and patients about EC. They must be reliable sources of information on EC and its proper use.

Pharmacists are in a particularly unique position to assist patients in need of EC. As frontline providers, they are in a position to offer support on many levels, including counseling patients, helping inform the community, and becoming advocates for improved access for low-income women and those younger than 17 years of age.

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