WEBINAR IN PRINT

A continuing education activity for pharmacists

Emergency Contraception: Clinical Aspects and Patient Care

This activity is supported by an educational grant from Perrigo.

Emergency Contraception: Clinical Aspects and Patient Care

Webinar in Print

In recent years, several over-the-counter emergency contraception products have entered the market. These include Plan B and other levonorgestrel-based generic alternatives. No longer are these products dispensed by pharmacists, nor are they subject to age restrictions, counseling requirements, and certain other guidelines that were imposed when Plan B was first approved. Yet, there is significant confusion, as well as misunderstanding and anxiety, among pharmacists as well as consumers regarding how emergency contraception works, when it can be effectively dispensed and used, and who can use it. It is essential that pharmacy professionals be able to consistently and authoritatively counsel patients about OTC emergency contraception products – regardless of whether the product is available OTC, behind-the-counter, or in a locked display. This CE activity provides pharmacists a thorough review of how these products are used, who may purchase them, and how they and their patients can obtain additional needed information.

Learning Objectives

The target audience for this activity is pharmacists. At the completion of this activity, the participant will be able to:

- List the currently available emergency contraception (EC) products and their OTC status
- Describe the mechanism of action and adverse effects of EC products
- Describe how patients obtain EC products, including age restrictions and specific state restrictions
- Outline counseling points for patients taking EC products – instructions for use, side effects, and implications
- Explain the specific FDA requirements and practice guidelines that govern the sale of EC products

Faculty

Mary Lynn Moody BSPharm
Director, Business Development
Drug Information Group
University of Illinois at Chicago
College of Pharmacy
Chicago, Illinois

James H. Wisner, BBA, MBA
President
Wisner Marketing Group, Inc.
Libertyville, Illinois

Accreditation

This CE activity is jointly provided by ProCE, Inc. and Wisner Marketing Group. ProCE is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ACPE Universal Activity Number 0221-9999-15-100-H01-P has been assigned to this knowledge-based home-study CE activity (initial release date 06-01-15). This activity is approved for 1.0 contact hour (0.1 CEU) in states that recognize ACPE providers. Completion of the evaluation and the post-test with a score of 70% or higher are required to receive CE credit. No partial credit will be given.

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ProCE, Inc.
848 W. Bartlett Road
Suite 3E
Bartlett, IL 60103
www.ProCE.com

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About the Faculty

Mary Lynn Moody, BSPharm

Mary Lynn Moody, BSPharm, is a Clinical Associate Professor in the Department of Pharmacy Practice at the University of Illinois at Chicago College of Pharmacy. She is also the Director of Business Development for the Drug Information Group. In this role, she is responsible for development and coordination of business relationships with clients of the Drug Information Group. Mary Lynn completed her pharmacy degree at the University of Illinois at Chicago and a PGY1 residency at Northwestern Memorial Hospital in Chicago.

James H. Wisner, BBA, MBA

Jim Wisner is President of the Wisner Marketing Group in Libertyville, Ill. He launched his company in 1999 after accruing over 30 years of senior management experience in the food and drug industry at Jewel Food Stores, Shaw's Super-markets, and Topco Associates, where he was responsible for the OTC product area and launched the Topco Pharmacy Program. He has developed several industry-wide research and education programs in consumer healthcare and other topics. Jim has contributed to numerous pharmacy education activities, focusing on self-care and patient behavior in the community pharmacy setting. Jim received his BBA in Marketing from the University of Notre Dame and his MBA from the Kellogg Graduate School of Management at Northwestern University.

Disclosures

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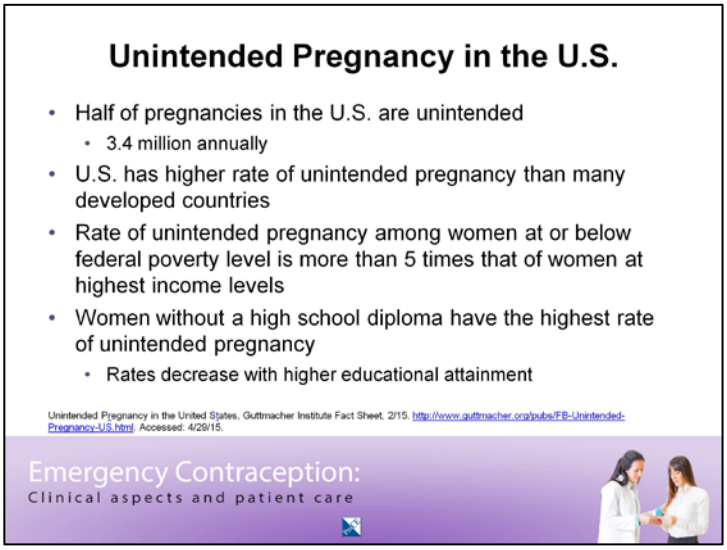
Over the past few years, probably no other drug topic has received as much attention or been in the news as much as the journey of emergency contraception (EC) products from prescription to OTC status. A maelstrom of legal, moral, clinical, and religious issues has created a measure of confusion among patients and pharmacists alike. This continuing pharmacy education activity will bring pharmacists up to date and enable them to better counsel patients seeking EC.



EC is, of course, a method to prevent unintended pregnancy. Half of the pregnancies in the U.S. are in fact, unintended. The U.S. has a higher rate of unintended pregnancy than those reported in many developed countries around the world. The rate among poor women is more than 5 times that of women at the highest income levels. And women without a high school diploma have the highest rate of all. The risk of unintended pregnancies can place a strain on public health resources, therefore creating a need for EC for many individuals.

Teen Pregnancy

- Unintended pregnancy rate for sexually active teens aged 15-17 is 147 per 1,000
- Rate for ages 18-19 is 162 per 1,000
- Unintended pregnancy rate among sexually active teens is more than twice that for all women
- Rate for all women, without regard for sexual activity, is 51 per 1,000

Finer LB. *Unintended Pregnancy Among U.S. Adolescents: Accounting for Sexual Activity.* J Adolesc Health. 2010 Sep;47(3):312-4. http://www.guttmacher.org/pubs/journals/JAH-Unintended-pregnancy.pdf. Accessed: 4/29/15.

Emergency Contraception:
Clinical aspects and patient care

The pregnancy rate for sexually active teens between the ages of 15 and 17 is 147 per 1,000. That rate increases to 162 per 1,000 for those aged 16 to 19. The unintended pregnancy rate among only those who are sexually active is more than twice the rate of that for all women. The rate for all women without regard for sexual activity is 51 per 1,000.

Unintended and Teen Births

- Unintended pregnancies cost federal and state governments $21 billion in 2010
- Without current publicly funded family planning programs, costs could have been 75% higher
- Unintended or teen pregnancy associated with:
  - Delayed prenatal care
  - Premature birth and low birth weight
  - Higher likelihood of incarceration

Sonfield A, Kost K. *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010.* New York: Guttmacher Institute, 2015.

Logan C, et al. The consequences of unintended childbearing: A white paper [Internet]. Washington: Child Trends, Inc.; 2007 May. Available from: http://thenationalcampaign.org/sites/default/files/resource-primary-download/consequences.pdf.

Hoffman S. By the Numbers: The Public Costs of Teen Childbearing. Washington: National Campaign to Prevent Teen Pregnancy; 2006. Available from: https://thenationalcampaign.org/resource/numbers

Emergency Contraception:
Clinical aspects and patient care

Unintended pregnancy cost federal and state governments $21 billion in 2010. That's the most recent data reported, and represents an increase from $11 billion in 2006. Without currently funded public family planning programs, those costs could have been 75% higher.

Unintended teen pregnancy has been associated with delayed prenatal care, premature birth and low birthrate, and a higher likelihood of incarceration. All of these outcomes have a significant social impact.

Benefits of Emergency Contraception

- Expanded access to EC could:
  - Reduce unintended pregnancy by up to 50%
  - Reduce abortions by 42%
  - Result in cost savings to payers, consumers
- Does not result in increased high-risk behavior

Current research indicates that neither abortions nor unintended pregnancies are reduced, mainly because people are not using EC after unprotected sex.

J Nurs Practitioner. 2007;3(7):470-474.

Emergency Contraception:
Clinical aspects and patient care

The availability of EC offers several benefits. Expanded access can reduce unintended pregnancies by as much as 50%, reduce abortions by 42%, and result in cost savings to payers and consumers. Most importantly, EC has been found *not* to result in increased high-risk behavior. Multiple studies suggest that an increase in high-risk behavior does not take place. However, it is not yet conclusive that the availability of EC has led to a reduction in abortions or unintended pregnancy.

Who Needs EC?

- Women experiencing contraceptive failure
  - Condom broke, slipped, or used incorrectly
  - Missed 2-3 doses of oral contraceptive
  - Victim of sexual assault
  - Contraceptive methods used inadequately
  - Failed to use any type of contraception

Obstet Gynecol. 2010; 115(5):1100-1109.
Pharmacy Today. 2010;50(6):48-60.

Emergency Contraception:
Clinical aspects and patient care

Who is it that needs EC? In general, it is women who experience contraceptive failure most commonly because a condom broke, slipped, or was used incorrectly. Others include women who have missed 2 or 3 doses of an oral contraceptive, victims of sexual assault, those who may have used contraceptive methods inadequately or incorrectly, and those who failed to use any type of contraception.

EC Use in United States

- 11% of sexually experienced women have used EC (2010)
  - 23% of women aged 20-24
  - 14% of women aged 15-19
- Up from 4% in 2002
- Reported uses:
  - 49% from unprotected sex
  - 45% from fear of method failure

Daniels K, et al. Use of emergency contraception among women aged 15–44: United States, 2006–2010. NCHS data brief, No. 112. Hyattsville, MD: National Center for Health Statistics. 2013.

Emergency Contraception:
Clinical aspects and patient care

In the U.S., 11% of sexually experienced women have used EC, according to a study published by the CDC in 2013, with data reported through 2010. The study indicated higher use by younger women—23% of women aged 20 to 24 and 14% of those aged 15 to 19. These numbers were up 4% from 2002. 49% reported their use of EC was as a result of unprotected sex, and 45% reported that it resulted from a fear that the method of contraception they used may have failed.

A more recent study done by the CDC is likely to be released by 2016. Other private studies and sales data indicate that EC use has changed significantly since the products became available OTC.

Opinions on EC

- Attitudes toward EC:
  - Most women believe it is effective
  - 92% believe it is safe
  - 95% would recommend to a friend
  - 75% reported convenient to use
- Survey of 14- to 19-year-olds shows they support use of EC:
  - In cases of rape (88%)
  - If condom breaks (82%)
  - If birth control is not used (76%)
  - If 1 oral contraceptive pill is missed (51%)

Pediatr Emerg Care. 2013; 29(4): 469-474.
Am J Obstet Gynecol. 2007;196:29.el-29.e6.

Emergency Contraception:
Clinical aspects and patient care

Most women believe that EC is effective, and 92% believe it is safe. Most would recommend it to a friend, and 75% report that it is convenient to use. Several studies have been done in this area, and findings have been very consistent.

A survey of 14- to 19-year-olds found that 88% support the use of EC in cases of rape. 82% would support it if a condom broke, 76% if birth control was not used, and 51% if one or more oral contraceptive pills were missed.

Contraceptive Use

Method	% of all women using[1]	Expected pregnancy rate with typical use[2]
Pill (combined estrogen/progestin)	17.1%	9
Tubal sterilization	16.5%	0.5
Male condom	10.2%	18
Vasectomy	6.2%	0.15
Intrauterine device	3.5%	0.2-0.8
Withdrawal	3.2%	22
Injectable	2.4%	6
All other methods[3]	3.1%	0.05-24
No method	37.8%	85

1. Women aged 15-44; 2. Rates may be lower with perfect method use; 3. Vaginal ring, patch, implant, fertility awareness-based methods, other

Guttmacher Institute. Fact Sheet: Contraceptive Use in the United States. August 2013. http://www.guttmacher.org/pubs/fb_contr_use.html.

Emergency Contraception:
Clinical aspects and patient care

The right-hand column of this chart shows the expected pregnancy rate with typical contraceptive use. That indicates the actual experience rate with these different forms of contraception; it does *not* indicate whether they were used correctly. If individuals use contraceptive forms correctly, the rates are much lower than what people typically experience. For example: condoms show the highest pregnancy rate; with perfect use, though, the 18% expected pregnancy rate would be closer to 2%. In the case of birth-control pills, when used correctly the anticipated pregnancy rate is 0.3%—significantly less than the actual experience. Since many individuals do not use other forms of contraception correctly, EC takes on greater importance.

Contraceptive Error

- 7.9 million women in the U.S. rely on condoms for birth control
- Significant failure rate (18%) with inconsistent or imperfect use
- Failure rates of condoms may be higher for adolescents than adults
- Study of male teens: 40% did not know how to use a condom

J Nurs Practitioner. 2007;3(7):470-474.

Sanders SA, et al.Condom use errors and problems: a global view. *Sexual Health* 2012; 9: 81–95. http://dx.doi.org/10.1071/SH11095

Emergency Contraception:
Clinical aspects and patient care

Contraceptive error is significant. The least effective method, condoms, is relied on by 7.9 million women in the U.S. as their primary means of birth control. There is a significant failure rate, which may be much higher for adolescents than adults. One study of male teens indicated that 40% did not know how to use a condom correctly.

History of Emergency Contraception

Emergency Contraception:
Clinical aspects and patient care

What Is Emergency Contraception?

- Generally an oral agent, taken as a single dose
- Used after normal contraceptive method fails, is not used, or is not available
- Not designed for routine use
- Most popular type contains the same active ingredient as conventional oral contraceptives
- Not an abortifacient

J Pediatr Gynecol. 2010;23(5):273-278.
Pharmacy Today. 2010;50(6):48-60.

Emergency Contraception:
Clinical aspects and patient care

Generally, we think of EC as an oral tablet taken as a single dose. It's normally used after contraceptive methods fail, after contraception is not used, or when it's just not available. EC is not designed for routine use.

The most popular types contain the same active ingredients as conventional oral contraceptives. And it's important to know that EC is not an abortifacient.

Yuzpe Regimen

- EC has been used since the 1970s
- Developed by A. Albert Yuzpe as a method of reducing unwanted pregnancies, including pregnancy from rape
  - First studies demonstrating safety and efficacy published in 1974
- Was standard EC treatment until levonorgestrel-only products became available
- High dose of combined progestin-estrogen oral contraceptive pills
  - 0.1 mg ethinyl estradiol and 0.5 mg levonorgestrel given within 72 hours of intercourse, repeated 12 hours later
- Effectiveness: 56% to 89%

Yuzpe AA, et al. Post coital contraception—A pilot study. J Reprod Med. 1974;13(2):53–8.
Contraception. 2010;82(5):404-409.
Pharmacy Today. 2010;50(6):48-60.

Emergency Contraception:
Clinical aspects and patient care

The original EC that has been in use since the 1970s was called the Yuzpe regimen. This regimen consisted of a high-dose combination of progestin and estrogen oral contraceptive pills. It contained 0.1 mg of ethinyl estradiol and 0.5 mg of levonorgestrel. This combination was administered within 72 hours after intercourse and was repeated in 12 hours.

Efficacy of the Yuzpe regimen was not great (56% to 89%). Nonetheless, it was the standard EC until levonorgestrel-based products became available.

Preven®

- First dedicated EC product
  - Approved by FDA in 1998
- Initial dose within 72 hours of unprotected intercourse; another dose 12 hours later
- Each 2-tablet dose contained 0.1 mg of ethinyl estradiol and 0.5 mg of levonorgestrel
- Discontinued in May 2004 due to availability of Plan B®, a progestin-only EC product

Pharmacy Today. 2010;50(6):48-60.
Drug Facts and Comparisons. 2011.

Emergency Contraception:
Clinical aspects and patient care

The first EC product approved by the FDA was called Preven (approved in 1998). This product was to be used within 72 hours of unprotected intercourse, and a second dose was given 12 hours later. Similar to the Yuzpe regimen, each 2-tablet dose contained 0.1 mg of ethinyl estradiol and 0.5 mg of levonorgestrel.

Preven was discontinued in 2004 when Plan B, a progestin-only product, became commercially available.

Levonorgestrel

- Original progestin-only product approved by FDA in 1999 as Plan B
- Originally contained two 0.75-mg doses of levonorgestrel taken 12 hours apart
  - Reformulated to single 1.5-mg dose
  - Does not contain estrogen
- Reduces chances of pregnancy if taken within 72 hours of unprotected intercourse
- Branded generic approved in 2009
- Generic levonorgestrel available in 2011
- Approved for unrestricted over-the-counter sales in 2013

Adv Ther. 2010;28(1):1-4.
Drug Facts and Comparisons. 2014.

Emergency Contraception:
Clinical aspects and patient care

Levonorgestrel is the original progestin-only product, approved by the FDA in 1999 as Plan B. Originally, the product consisted of two 0.75-mg doses of levonorgestrel that were taken 12 hours apart. It was reformulated to a single 1.5-mg dose. Plan B does not contain estrogen.

Levonorgestrel reduces the chances of pregnancy if taken within 72 hours of unprotected intercourse. A generic Plan B became available in 2009, and several generic levonorgestrel products became available in 2011. In 2013, levonorgestrel was approved for unrestricted sale over the counter.

Ulipristal Acetate

- Approved by FDA in 2010
- Selective progesterone receptor modulator
- Effective for 120 hours (5 days) after intercourse, regardless of whether hormonal surge has occurred
- Greater efficacy than levonorgestrel

Drug Facts and Comparisons. 2014.

Emergency Contraception:
Clinical aspects and patient care

Ulipristal acetate was approved by the FDA in 2010. This product is available by prescription. It is a selective progesterone receptor modulator and has efficacy for up to 120 hours or 5 days after intercourse, regardless of whether a woman's hormonal surge has occurred. It demonstrates greater efficacy than levonorgestrel.

Emergency Contraception History

1972	Albert Yuzpe begins studies of combined estrogen-progestin regimen for EC
September 1, 1998	FDA approves Preven® Emergency Contraception Kit
July 28, 1999	Plan B Tablets approved for prescription sale
May 2004	Preven® Discontinued
August 24, 2006	Plan B approved for non-prescription sale for women aged 18 and older
July 10, 2009	Plan B One-Step approved; Plan B products approved for non-prescription sale to women aged 17 or older
August 13, 2010	ella® approved for prescription sales
April 30, 2013	Plan B One-Step approved for non-prescription sale to women aged 15 or older
June 20, 2013	Plan B One-Step approved for OTC sales without age restriction
February 25, 2014	Generic one-pill EC products approved for unrestricted OTC sales

Emergency Contraception:
Clinical aspects and patient care

Here is an overview of the history of EC. In April 2013, Plan B One Step was approved for nonprescription sale to women aged 15 and older. In June 2013, it was approved for OTC sale without any age restriction. In February 2014, generic single-pill EC products were approved for unrestricted OTC sale to individuals regardless of age.

Current EC Products

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Clinical aspects and patient care

Currently Available EC Products

Active Ingredient	Product	Dosage	Dosing Window	OTC Status	Prescription Required?
Levonorgestrel	Plan B One-Step	One 1.5-mg white pill	72 hours	No restriction	None, regardless of age
	My Way	One 1.5-mg white pill		"For women 17 years of age or older"*	
	Next Choice One Dose	One 1.5-mg peach pill		"For women 17 years of age or older"*	
	Take Action	One 1.5-mg white pill		No restriction	
	Option 2	One 1.5-mg white pill		"For women 17 years of age or older"*	
Ulipristal Acetate	Ella	One 30-mg white pill	120 hours	Not available OTC	Yes, for women of any age

* Statement required by FDA for packaging approval, but no sales restrictions exist

Drug Facts and Comparisons. 2014.

Emergency Contraception:
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This chart provides an overview of the various EC products that are available in the U.S. As noted in the last column, none of these agents, with the exception of Ella, requires a prescription regardless of the age of the patient.

Other Products

- Products that are bioequivalent to Plan B One-Step:
  - After Pill only available for sale online
  - Some retailers have their own brands
- Products in the original 2-tablet formulation (two 0.75-mg doses of levonorgestrel taken 12 hours apart) may still be in stock in some pharmacies
- A 10-mg dose of mifepristone has also been used for emergency contraception, but is no longer common in the United States

International Family Planning Perspectives. Volume 29, Number 2, June 2003

Emergency Contraception:
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Some of the other products include After Pill, which is a bioequivalent form of Plan B One-Step. This product is only available for sale online. Certain retailers may have their own brands that are bioequivalent to Plan B One-Step. Pharmacists should be aware of those equivalent brands, so they can advise patients. Products in the original 2-tablet formulation—that is, tablets containing two 0.75-mg doses of levonorgestrel taken 12 hours apart—may still be available in some pharmacies. In addition, a 10-mg dose of mifepristone has been used in the past for EC; however, it is no longer commonly used in the U.S.

Copper-T IUD

- Intrauterine device used by some women for regular birth control can be used for EC
- Doctor must insert in patient
  - Can be done up to 5 days after unprotected intercourse
- Reduces risk of pregnancy by >99%
  - More effective than all other forms of EC
- Can be left in place as normal contraceptive for up to 10 years

Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/info/eciud.html, accessed February 9, 2014..

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Another form of EC—and probably the most effective—is the intrauterine device, or Copper T IUD. This device is used by many women for regular birth control but can also be used for EC. A physician must insert the IUD, and this can be done up to 5 days after unprotected intercourse. It reduces the risk of pregnancy by over 99%. Once the IUD has been placed, it can remain in the patient for up to 10 years and be used as a normal contraceptive.

How EC Works

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What Is Levonorgestrel?

- Synthetic progestin
- Active ingredient in many daily oral contraceptives
- Oral agent, taken as a single dose or two doses 12 hours apart
- Can prevent pregnancy after unprotected intercourse
- Two-tablet formulations are generics or store brands
- One-tablet formulation brands include:
  - Plan B One-Step
  - My Way
  - Next Choice One Dose
  - Option2
  - Take Action
- Not an abortifacient

J Pediatr Adolesc Gynecol. 2010;23(5):273-278.
Pharmacy Today. 2010;50(6):48-60.

Emergency Contraception:
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Levonorgestrel is a synthetic progestin and is the active ingredient in many traditional oral contraceptives. It is an oral agent that can be taken either as a single dose or as 2 doses taken 12 hours apart. It has demonstrated efficacy in preventing pregnancy after unprotected intercourse. Several single-tablet formulations are available, including Plan B One-Step, My Way, Next Choice One Dose, Option 2, or Take Action. Levonorgestrel-based EC is *not* an abortifacient.

Mechanism of Action: Levonorgestrel

- Similar to other hormonal contraceptives
- Varies depending on day of menstrual cycle
- Inhibits or delays ovulation
- Prevents pregnancy during the 5 or more days between intercourse and implantation
- Not effective after implantation
- Levonorgestrel does NOT interrupt an established pregnancy

Obstet Gynecol 2010;115(5):1100-1109.

Emergency Contraception:
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Let's look at the mechanism of action of levonorgestrel. It is similar to other oral hormonal contraceptives. Efficacy varies depending on the day of the menstrual cycle. It either inhibits or delays ovulation and prevents pregnancy during the 5 or more days between intercourse and implantation. This product is not effective after implantation; therefore, it does not interrupt an established pregnancy.

Ulipristal Acetate

- Active ingredient in ella®, an EC product that is available by prescription only
- Can prevent pregnancy after unprotected intercourse
- Can be taken up to 5 days after unprotected sex and is believed to be more effective than levonorgestrel-based emergency contraceptives
- Not an abortifacient

Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/info/ecp.html, accessed: 2/4/14.

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Ulipristal acetate, or Ella, is the only EC product that is available by prescription. It also can prevent pregnancy after unprotected intercourse. It can be taken up to 5 days after unprotected intercourse and is believed to be more effective than levonorgestrel-based EC. As with levonorgestrel, it is not an abortifacient.

Mechanism of Action: Ulipristal Acetate

- Selective progesterone receptor modulator
- Reversibly blocks the progesterone receptor and inhibits or delays ovulation
- Not effective after implantation
- Does NOT interrupt an established pregnancy

Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/pills/ella.html, accessed: 2/7/14.

Emergency Contraception:
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Ulipristal acetate is a selective progesterone receptor modulator that reversibly blocks the progesterone receptor and inhibits or delays ovulation. Like levonorgestrel, it is not effective after implantation and does not interrupt an established pregnancy.

EC Dosing

- Single-dose levonorgestrel
  - One 1.5-mg tablet
  - As soon as possible after unprotected intercourse (within 72 hours)
- Ella
  - One 30-mg tablet
  - As soon as possible after unprotected intercourse (within 120 hours)

Lancet 2002;360:1803-1810.
Contraception2002;66:269-273.
Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/questions/ecsafe.html.

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Single-dose levonorgestrel is 1 tablet taken as soon as possible after unprotected intercourse. It is generally recommended that it be used within 72 hours of unprotected sex. Ella is a single 30-mg tablet that is administered as soon as possible after unprotected intercourse. But it can be taken up to 5 days after unprotected sex.

EC Risk Factors

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Contraindications: Ulipristal Acetate and Progestin-only Pills

- Women with contraindications to oral contraceptives can use EC, including women with:
  - Previous ectopic pregnancy
  - Heart disease
  - Migraines
  - Liver disease
  - Breastfeeding
- There is no medical condition in which risks outweigh benefits of EC according to WHO

Obstet Gynecol 2010;115(5):1100-1109.
Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/questions/ecsafe.html, accessed: 2/4/14.

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Women who have contraindications to conventional oral contraceptives can still use EC. This group includes women who have had an ectopic pregnancy, those who have heart disease, a history of migraine, or liver disease, or women who are breastfeeding. According to the World Health Organization, there is no medical condition in which the risks of EC outweigh its benefits.

Contraindications (cont'd)

- Known or suspected pregnancy
- Hypersensitivity to any component of the drug

Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/emergency-contraception.html, accessed January 30, 2014.

Emergency Contraception:
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The only real contraindication to EC is a known or suspected pregnancy, or hypersensitivity to any component of the drug.

Effectiveness in Larger Women

- EC may be less effective in women who are overweight or obese
- Efficacy decreases linearly with weight
- Levonorgestrel-based EC may not be as effective in women with BMI over 26
- Ulipristal acetate loses effectiveness for BMI over 35
- For an average woman (5'4" tall):
  - BMI of 26 is >150 lbs
  - BMI of 35 is >200 lbs

Contraception. 2015 Feb;91(2):97-104. doi: 10.1016/j.contraception.2014.11.001. Epub 2014 Nov 8.

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It is important to be aware of differences in effectiveness of EC in larger, heavier women. Randomized clinical trials have found that EC may be less effective in overweight and obese women. Studies have shown that efficacy decreases linearly with weight.

Levonorgestrel-based EC may not be as effective in women with a BMI over 26. By comparison, ulipristal acetate loses its effectiveness in women with a BMI over 35. As a point of reference, for a woman of average height (5'4"), weight of 150 pounds would result in a BMI of 26; weight >200 pounds would result in a BMI of 35.

Most Common Side Effects

Adverse Effect	Frequency with Levonorgestrel 1.5 mg
Heavier menstrual bleeding	30.9%
Nausea	13.7%
Fatigue	13.3%
Lower abdominal pain	13.3%
Headache	10.3%
Dizziness	9.6%
Breast tenderness	8.2%
Delay of menses (>7 days)	4.5%

Drug Facts and Comparisons. 2014.

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What are the most common side effects reported with EC, particularly levonorgestrel? 30% of women report heavier menstrual bleeding, and 13% report nausea, fatigue, or lower abdominal pain. Headache and dizziness occur in about 10% of women, and breast tenderness is reported in 8%. About 4.5% of patients report their menstrual cycle is delayed by >7 days.

Vomiting and Antiemetics

- Patients may experience vomiting after EC use
- If patient vomits within 2 hours of using any product, consider repeating the dose
- Consider using an antiemetic 1 hour prior to EC use

Drug Facts and Comparisons, 2014.
Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/questions/dose.html, accessed: 2/4/14.

Emergency Contraception:
Clinical aspects and patient care

Some women may experience nausea or vomiting when they use EC. If a patient vomits within 2 hours of using any EC product, you should consider repeating the dose. In addition, women who have a history of nausea and vomiting may want to consider using an antiemetic 1 hour prior to EC use.

Effects on Menses

- Patient should have a normal period within the next month after taking EC
- Length of the monthly menstrual cycle may change with EC
  - Next period may come as much as 1 week earlier or later
- Some women will experience spotting after EC use
- 13% have heavier-than-normal menstrual bleeding
- 12% have lighter-than-normal menstrual bleeding
- If menses is delayed by >7 days, contact physician and recommend a pregnancy test

Drug Facts and Comparisons, 2014.

Emergency Contraception:
Clinical aspects and patient care

What is the effect of EC on the menstrual cycle? The patient should have a normal period within the next month after taking EC. However, the length of the monthly menstrual cycle may change after taking EC. Sometimes the period might be 1 week earlier or later. If menses is delayed by >7 days, it is important to contact a physician and consider obtaining a pregnancy test. Some women will experience spotting after EC use. About 13% have greater bleeding than normal, and about 12% have bleeding lighter than normal.

Ectopic Pregnancy

- Although a relationship has been suggested, no evidence indicates ectopic pregnancies increase with the use of EC
- EC use reduces the risk of pregnancy and therefore reduces the risk of having an ectopic pregnancy
- Ectopic pregnancies can still occur after a woman uses EC
- Symptoms include:
  - Irregular bleeding
  - Lower abdominal or pelvic pain
  - Dizziness
- Immediate medical attention is required for patients exhibiting these symptoms

Drug Facts and Comparisons. 2011. Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/questions/ecectopic.html, accessed: 2/4/14.

Emergency Contraception:
Clinical aspects and patient care

Ectopic pregnancy is a condition that requires immediate medical attention. Although a relationship has been suggested between ectopic pregnancy and EC, there is no good evidence to show an increased risk. EC actually reduces the risk of pregnancy, so it could be argued that it reduces the risk of ectopic pregnancy. Nonetheless, ectopic pregnancies can occur after a woman uses EC, so they need to be aware of symptoms: irregular bleeding, lower abdominal or pelvic pain, and dizziness. Patients who exhibit any of these symptoms should immediately seek medical attention.

Effectiveness

- Labels indicate that progestin-only EC pills prevent 7 of 8 pregnancies that otherwise would have occurred
- If progestin-only pills are taken within the first 24 hours after sex, the pregnancy rate is reduced to <5%
- Pregnancy risk is even lower with ella
- Clinical studies indicate that ella is effective for 5 days after unprotected sex
  - What matters most is where a woman is in her cycle; therefore, medication should be taken as quickly as possible

Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/questions/eceffect.html, accessed: 2/4/14.

Emergency Contraception:
Clinical aspects and patient care

Looking at the effectiveness of EC, labels indicate that the progestin-only product prevents 7 of 8 pregnancies that otherwise would have occurred. If progestin-only pills are taken in the first 24 hours after sex, the pregnancy rate is reduced to <5%.

Pregnancy risk is even lower with Ella. Clinical studies indicate that Ella is effective up to 5 days after unprotected sex.

It's important to reinforce that any of these medications should be taken as soon as possible.

Drug Interactions

- CYP 3A4 inducers
  - May decrease effectiveness of progestin-only contraceptives
  - Barbiturates, carbamazepine, felbamate, phenytoin, rifampin, St. John's wort
- Protease inhibitors/NNRTI
  - Changes in progestin serum levels have been noted
  - Increase or decrease in level

Drug Facts and Comparisons, 2011.

Emergency Contraception:
Clinical aspects and patient care

When talking to customers about the use of EC, it is important that you consider discussing potential drug interactions. Drugs that are CYP 3A4 inducers can decrease the effectiveness of progestin-only contraceptives. These include barbiturates, carbamazepine, felbamate, phenytoin, rifampin, and St. John's wort. Protease inhibitors and non-nucleoside reverse transcriptase inhibitors can change (increase or decrease) progestin serum levels. If a patient is using any of these medications, it is important to review the potential risks of EC.

Pregnancy and/or Lactation

- Pregnancy Category X
- Not effective in terminating existing pregnancy
- No effects on fetal development or infant growth or development observed with progestin-only contraceptives
- Nursing mothers may use progestin-only contraceptive pills
  - Some hormones may be passed through the breast milk, but the child will not be affected
- ella (ulipristal acetate) is not recommended because risks to the child are unknown

Drug Facts and Comparisons, 2014.
Office of Population Research, Princeton University, Association of Reproductive Health Professionals, http://ec.princeton.edu/questions/ecfeeding.html, accessed: 2/4/14.

Emergency Contraception:
Clinical aspects and patient care

All EC products are pregnancy category X. They should not be administered to a woman who is pregnant. These products are not effective in terminating an existing pregnancy. There is no evidence that these products have any effect on fetal development or on infant growth. Nursing mothers may use progestin-only contraceptive pills. Although some of the hormone may be passed on through breast milk, the amount is not significant enough to harm the child. Ella, or ulipristal acetate, is not recommended for use by breastfeeding women because the risks to the child are unknown.

Patient Access

Emergency Contraception:
Clinical aspects and patient care

ID Requirement/Dual Labeling

- For levonorgestrel-based EC products (both Plan B One-Step and generics), customers are no longer required to provide proof of age prior to purchase without a prescription
- Despite labeling suggesting they are intended for women age 17 or older, branded generics are available for sale to women of any age without restriction

Princeton University, Office of population research. The emergency contraception website. http://ec.princeton.edu/questions/QA-OTC-access.html. Accessed Feb 4, 2014.

Emergency Contraception:
Clinical aspects and patient care

For levonorgestrel-based EC products—both Plan B One-Step and generics—customers are no longer required to provide proof of age prior to purchase without a prescription. Despite this, labeling on most of the branded generics (all products except Plan B One-Step and Take Action) suggest that the product is intended for women aged 17 or older. In fact, these products are available for sale to women of any age without restriction.

Males

- Laws do not specify that EC must be sold to the intended user
- Males may purchase EC, subject to the same restrictions as women

Princeton University, Office of population research. The emergency contraception website. http://ec.princeton.edu/questions/QA-OTC-access.html. Accessed Feb 4, 2014.

Emergency Contraception:
Clinical aspects and patient care

What about males? The laws do not specify that EC must be sold to the intended user. Males may purchase EC subject to the same restrictions as women. In a poll conducted in 2014, only 37% of pharmacists knew that men of any age could purchase EC products. Additionally, 10% of the pharmacists admitted to not knowing if there was a regulation against sale to males. More than half answered with a misinformed response.

State Policies Expanding Access

- Emergency rooms are required to:
  - Dispense EC on request in 13 states, plus DC (CA, CT, DC, HI, MA, MN, NJ, NM, NY, OR, PA*, SC, UT, WA, WI)
  - Provide information upon request in 17 states, plus DC (states listed above, minus SC, plus AR, CO, IL, TX)
- Pharmacists may prescribe EC under collaborative practice agreement or state-approved protocol in 9 states (AK, CA, HI, ME, MA, NH, NM, VT, WA)
- Pharmacists or pharmacies are required to fill all valid EC prescriptions in 5 states (CA, IL, NJ, WA, WI)

* Hospitals with religious or moral objections must immediately transport patient to hospital that will fulfill request.

Guttmacher Institute. State policies in brief: emergency contraception. April 1, 2015. Accessed on April 29, 2015.

Emergency Contraception:
Clinical aspects and patient care

Access policies do differ in some states. Emergency Rooms are required to dispense EC on request in 13 states and the District of Columbia. They have to provide information on request in 17 states plus the District of Columbia and many of these are the same states as those required to dispense EC. Pharmacists can prescribe EC products under a collaborative practice agreement or state approved protocols in the 9 states listed here. Pharmacists or pharmacies are required to fill all valid EC prescriptions in 5 states. Now you may notice that Illinois, which is in a unique situation, appears on several of these lists. Their regulations, as a result of several court hearings and trials, have created a situation where *pharmacists* may object under a pharmacist conscience exception, but the *pharmacy* is still required to provide EC products to patients who request them.

Pharmacy Access: Collaborative Practice Agreements and State Protocols

- Allows pharmacist to write a prescription and dispense drug directly to a patient
- May require special training and/or collaborative practice agreement with local physician

State	Collaborative Practice Agreement	State-Approved Protocol
Alaska	X	
California	X	X
Hawaii	X	
Maine		X
Massachusetts	X	
New Hampshire	X	
New Mexico		X
Vermont	X	
Washington	X	

Guttmacher Institute. State policies in brief: emergency contraception. April 1, 2015. Accessed on April 29, 2015.

Emergency Contraception:
Clinical aspects and patient care

Collaborative practice agreements and state protocols are in effect in a number of states. These allow pharmacists to write prescriptions and dispense drugs directly to patients. Some states may require special training or collaborative practice agreements with a local physician.

If EC is principally purchased OTC, why are there provisions for prescription dispensing? There are two reasons: In some cases it may involve Ella, which is available by prescription only. And, some individuals seek a prescription because their insurance policies may provide reimbursement.

Benefits of Collaborative Practice

- Unrestricted OTC availability of EC may suggest that pharmacy access via collaborative practice or state protocol is no longer needed; this is not true
- Emergency contraception is expensive for many women
- Rates of unintended pregnancy are higher among both low-income women and younger women, for whom cost may be prohibitive
- Providing EC via prescription may allow many women to submit purchase through their health insurance, defraying cost of treatment

Finer LB, Zolna MR. Am J Public Health. 2014, 104(S1): S44-S48.

Emergency Contraception:
Clinical aspects and patient care

Unrestricted OTC availability may suggest that access through a collaborative practice or state protocol is not needed. However, these initiatives still have value in the case of EC. For many women, EC is expensive. Rates of unintended pregnancy are higher among lower income women and younger women, for whom cost may be a prohibitive barrier to access. Providing EC via prescription may allow many women to submit the purchase through their health insurance, which defrays the cost of the treatment and makes it more accessible. It is important for pharmacists to regularly monitor specific regulations in their states. They change from time to time, and may impact how patients should be counseled.

Barriers to Access

Emergency Contraception:
Clinical aspects and patient care

OTC Is Not Universal

- Not all pharmacies sell EC over the counter
- 2014 survey:
  - 22% of pharmacists indicated they provided EC in their store's aisles without restriction
- December 2014 follow up:
  - Products were displayed in family planning section in 38% of stores
  - Another 5% placed products in the feminine care section
  - 57% of stores did not display products in the store aisles

Levonorgestrel Education and Research Network. Emergency Contraception Pharmacist Survey. October 2014.
Levonorgestrel Education and Research Network. Emergency Contraception Pharmacy Audits. December 2014.

Emergency Contraception:
Clinical aspects and patient care

OTC status does not make EC universal. Not all pharmacies or drug stores sell EC products OTC. In an October 2014 survey, just 22% of pharmacists indicated that they provided EC products in their stores aisles without restriction.
In a follow-up audit done in December 2014, products were displayed in the family planning sections in 38% of stores. Another 5% placed products in the feminine care section. In 57% of stores, products were not displayed in store aisles and had to be requested through the pharmacy.

State Laws Restricting Access

- Laws exclude EC from the Medicaid Family Planning Expansion (TX) or the Contraceptive Coverage Mandate (AR, NC)
- Pharmacists or pharmacies can refuse to fill EC prescriptions in AZ, AR, GA, ID, IL, MS, and SD
- In OK, a policy that requires a prescription for all women aged 16 and under is currently suspended pending the outcome of litigation

Guttmacher Institute. State policies in brief: emergency contraception. January 1, 2014. Accessed on January 30, 2014.

Emergency Contraception:
Clinical aspects and patient care

Some state laws may restrict access. Laws in 3 states exclude EC from the Medicaid family planning expansion or the contraceptive coverage mandate. Pharmacists or pharmacies can refuse to fill EC prescriptions in 7 states, under what is often referred to as "pharmacist conscience" acts. In Oklahoma, there is a regulation that requires a prescription for all women aged 16 and under. This statute was recently suspended pending the outcome of litigation. Pharmacists in Oklahoma should monitor the resolution of this matter.

Barriers to Access: Availability

- If EC is not offered as a true OTC product, it may limit access to women who need it
  - Many women are embarrassed to ask a pharmacist or store employee for the product
  - Access may be limited to hours that a pharmacist is on duty
- Not all pharmacies carry EC
  - Becomes a significant issue in rural areas

Emergency Contraception:
Clinical aspects and patient care

Barriers to access can also include availability. This may be the most significant barrier of all. If EC is not offered as a true over-the-counter product, access to women who need it is limited. Many women are embarrassed to ask a pharmacist or store employee for the product. Access may also be limited to the hours that the pharmacist is on duty. In addition, not all pharmacies carry EC. This can become a significant issue in rural areas where the nearest pharmacy may be located a long distance from the individual seeking the product. Some of the EC product websites offer a store locator; this can be helpful to some women.

Barriers to Access: OTC Display

- December 2014 audit revealed that EC products may be on the shelf, but are not fully OTC
- Products displayed in a number of ways:
  - 22% were on a shelf, available to take
  - 56% were in a theft-deterrent case or package
  - 11% were represented by a product card or instructions to see the pharmacist
  - 11% of stores were out of stock

Levonorgestrel Education and Research Network. Emergency Contraception Pharmacy Audits. December 2014.

Emergency Contraception:
Clinical aspects and patient care

Barriers to access can also stem from the way the OTC product is displayed in the store. In many cases, EC products may be on the shelf, but they're not readily available to take to the check out. They may be displayed in a number of ways. In a recent store audit, just 22% of stores had product on the shelf available for the customer. In 56% of stores, EC was in a theft-deterrent case or package; 11% provided a product card or instructions to see the pharmacist; and 11% of the stores were out of stock.

Barriers to Access: Price

- Cost of EC can be prohibitive for many women who might need it
  - Low-income women
  - College students
- 2013 pharmacy audit:
  - Average observed cost of Plan B was $49
  - Generics (both branded and unbranded) averaged about $8 less
- Counsel patients that cheaper alternatives exist
- Maintaining regular stock of generic options will increase access for patients

Pharmacy Today. 2010;50(6):48-60.
Levonorgestrel Education and Research Network. Emergency Contraception Pharmacy Audits. December 2014.

Emergency Contraception:
Clinical aspects and patient care

Price can also be a barrier to access. The cost of EC products, which typically runs close to $50, can be prohibitive for many women. This may include low-income women and college students. In another pharmacy audit, the average price of Plan B One-Step (the branded product) was $49. The generic alternatives, both branded and unbranded, typically averaged about $8 to $10 less. Pharmacists should advise patients if a less-expensive alternative exists at their location, the same as for generic prescription drugs. Maintaining a regular stock or carrying a second option can increase access for patients when price is an issue.

Barriers to Access: Pharmacist Knowledge

- A recent study had callers pose as 17-year-olds to ask pharmacies about obtaining EC
  - 19% of callers were told it would be impossible to obtain EC under any circumstances
  - 43% were given incorrect information regarding the age required for a woman to purchase EC without prescription
- Survey authors identified 4 major themes:
  - Ethical bias (e.g., personal or religious)
  - Confusion on dispensing regulations
  - Creation of false barriers to access
  - Issues regarding confidentiality

J Adolesc Health. 2014; 54(1):14-19.
Pediatrics. 2012; 129(4):624-629.

Emergency Contraception:
Clinical aspects and patient care

Barriers to access can involve a pharmacist's knowledge and understanding of the regulations. One recent study had callers pose as 17-year-olds to ask pharmacists about obtaining EC. 19% were told that it would be impossible to obtain EC under any circumstances. 43% were given incorrect information regarding the age at which a woman could purchase EC without a prescription.

The authors of this survey identified four major themes:

- Ethical bias on the part of the pharmacist.
- Confusion on the dispensing regulations.
- False barriers to access or misinterpretations.
- Issues regarding confidentiality.

Barriers to Access: Confidentiality

- Many women are embarrassed to ask for EC
- Judgmental behavior by pharmacists plays a role
- Restrictions on OTC sales may prevent women from obtaining EC
  - Behind-the-counter access
  - Need to find assistance obtaining product from theft-deterrent case
  - Belief that purchase can be reported

Pharmacotherapy. 2013;33(5):549-557.

Emergency Contraception:
Clinical aspects and patient care

Confidentiality is important to many patients. Many are embarrassed to ask for EC products. Pharmacists may exhibit judgmental behavior, whether it's overt or not, when they are interacting with women who request the product. In addition, restrictions on OTC sales may prevent women from obtaining EC. These include the products being available only behind-the-counter, the need to find assistance in obtaining a product from a theft-deterrent case, and a belief that somehow the purchase will be reported. As an example, a store carried EC products in a secured case. Nearby was a button to press for assistance to open the case. This prompted a loudspeaker announcement: "Assistance needed in the family planning aisle," creating an awkward situation for the customer. Be sure to raise sensitivity not only with pharmacy staff, but also with other store employees who may interact with customers seeking EC.

Patient Counseling

Emergency Contraception:
Clinical aspects and patient care

Counseling

- Many women do not know that pregnancy can be prevented after sex
- U.S. has one of the highest rates of unintended pregnancy in any developed country, yet just 11% of women have used EC
  - The most recent published data on EC use is from 2010
  - A 2014 consumer survey found that 37% of respondents had used EC, suggesting that increased OTC availability has led to an increase in EC use
- Pharmacists have unique opportunities to educate patients who ask for EC

Vital Health Stat 23(29). 2010.
Levonorgestrel Education and Research Network. Emergency Contraception Consumer Survey. September 2014

Emergency Contraception:
Clinical aspects and patient care

Many women do not know that pregnancy can be prevented after sex; this provides an opportunity for additional patient counseling. Pharmacists have a unique opportunity to educate their patients who come in for EC. Despite one of the highest rates of unintended pregnancy of any developed country, only 11% of U.S. women have used EC and many are unfamiliar with the products available. A consumer survey conducted in 2014 showed that 37% of 430 respondents had used EC. Thus, there may be an increased uptake of EC now that it is available over-the-counter. While more women may be aware of its availability, there are now many more who seek these products at the pharmacy.

Pharmacist Knowledge

- Despite the impact of EC treatment for women, many pharmacists are not well versed on the topic
- Misinformation can have consequences for women seeking EC treatment
- A survey of 132 pharmacists found that:
  - 83% could not correctly name the mechanism of action
  - More than a third (35%) underestimated the time frame in which EC treatment can be effective
  - More than 3 in 5 were not aware that EC was available to women of any age without prescription
  - Less than 2 in 5 knew that males could also purchase EC

Levonorgestrel Education and Research Network. Emergency Contraception Pharmacist Survey. October 2014 .

Emergency Contraception:
Clinical aspects and patient care

It is important that pharmacists be knowledgeable about this topic. Despite the impact that EC treatment has on women, many pharmacists may not be well versed. Misinformation can have a significant impact for women who are seeking EC treatment.

In a study of 132 pharmacists, 83% could not correctly name the mechanism of action, and 35% underestimated the time frame in which EC treatment can be effective. More than 3 in 5 pharmacists were not aware that EC was available to women of any age without a prescription. And less than 2 in 5 knew that males could also purchase EC.

Counseling: Safe Sexual Practices

- You may counsel your patients on their use of routine contraceptives
- Explain that EC does not protect against sexually transmitted infections
- Encourage patient to discuss contraception with healthcare provider

Emergency Contraception:
Clinical aspects and patient care

When counseling patients who are purchasing EC, pharmacists can also discuss safe sexual practices. Patients can be counseled on their routine use of contraceptives and encouraged to discuss contraception with their healthcare providers. Remind patients that EC does not protect against sexually transmitted diseases, and ensure that they understand the value of using condoms.

Resuming Birth Control

- Hormonal contraception: oral contraceptives, transdermal patch, vaginal ring
  - Resume these methods the day after EC
  - Use backup contraception (condom) for 7 days
- Non-hormonal contraception: condoms, diaphragm, cervical cap
  - Resume these methods right away

Zeiman M. Patient information: Emergency contraception (morning after pill) In: UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2011.

Emergency Contraception:
Clinical aspects and patient care

In addition safe sexual practices, the pharmacist may want to clarify when more traditional birth control should be resumed. Hormonal methods include oral contraceptives, the transdermal patch, and the vaginal ring. These methods can be resumed the day after the patient ingests EC. Backup contraception, such as a condom, should be used for 7 days after resuming hormonal contraceptive products. Non-hormonal protection, such as a condom, diaphragm, or cervical cap, can be resumed right away.

On-Hand Supply

- Counsel your patient to keep a supply of EC on hand at home, in case of emergency
- Increases convenience
- 53% of women prefer to have a supply at home
- Encourages prompt initiation of treatment
- Reinforce that this is not for routine birth control

Am J Obstet Gynecol. 2007;196:29.e1-29.e6

Emergency Contraception:
Clinical aspects and patient care

Pharmacists may also want to talk to their patients about keeping a supply on hand at home. Some women like the convenience of having the product available in case of an emergency. 53% of women prefer to keep a supply at home. Doing so encourages prompt initiation of treatment and reinforces that it is not to be used for routine birth control. For patients who are taking oral contraceptives, the pharmacist can initiate a conversation about EC (assuming a comfortable relationship) or have a sign in the pharmacy that says something like "Ask me about emergency contraception."

More Information

- Keep informational brochures in your pharmacy for patients who may be too nervous to ask, or who have more questions
- Additional resources can be found at:
  - planbonestep.com
  - mywaypill.com
  - mynextchoiceonedose.com
  - option2.com
  - afterpill.com
  - ellanow.com
  - kff.org
  - cecinfo.org

Emergency Contraception:
Clinical aspects and patient care

Keeping a variety of informational brochures in your pharmacy is very useful. Some customers may be too nervous or embarrassed to ask about EC. Or they may just have more questions. You can also obtain additional resources online. Several websites are listed here for additional information.

Continuing Education for this activity is processed through the ProCE online CE Center.
To receive CE credit:

- Go to www.ProCE.com/EC
- Click on "Post Test/Evaluation" to enroll and complete the Post Test and Evaluation

POST TEST

1. **Which of the following agents is available as an over-the-counter (OTC) medication for women of any age?**
   a. Plan B
   b. Next Choice One Dose
   c. My Way
   d. All of the above

2. **All single-tablet levonorgestrel emergency contraceptive (EC) products are available OTC without any sales restrictions based on age or gender.**
   a. True
   b. False

3. **How many states allow pharmacists to prescribe EC products under collaborative practice agreements?**
   a. 5
   b. 9
   c. 13
   d. 19

4. **In a recent store audit survey, what percentage of stores had EC products on the shelf and available for purchase without assistance from the pharmacy?**
   a. 11%
   b. 22%
   c. 47%
   d. 56%

5. **What type of drug may decrease the effectiveness of progestin-only contraceptives?**
   a. CYP 3A4 inducers
   b. CYP 3A4 inhibitors
   c. CYP 2D6 inducers
   d. CYP 2D6 inhibitors

6. **J.W. is a 31-year-old woman who takes oral contraceptives. She missed two pills and has come to your store to obtain EC. When counseling her, what do you tell her about resuming her oral contraceptive?**
   a. Resume her oral contraceptive 2 days after EC, and use back-up contraception (condoms) for 21 days.
   b. Resume her oral contraceptive the day after EC, and use back-up contraception (condoms) for 7 days.
   c. Resume her oral contraceptive the day after EC use. No need for back-up contraception.
   d. Resume her oral contraceptive 1 week after EC, and use back-up contraception (condoms) for the rest of the month.

7. **L.M. is a 22-year-old woman who currently uses condoms for birth control. She is interested in EC and having a supply at home in case she has a problem with a condom breaking. She is worried about using EC since she suffers from severe migraines and her physician will not let her use oral contraceptives as birth control. What do you tell her?**
   a. EC has same ingredient as oral contraceptive so she cannot use it.
   b. There is no medical condition in which the risk outweighs the benefits of EC.
   c. She may only use the prescription-strength EC.
   d. None of the above

8. **EC does not interfere with an established pregnancy.**
   a. True
   b. False

9. **One of the most common side effects of EC is nausea. If a patient experiences vomiting within 2 hours of the dose, what should she do?**
   a. Call her physician
   b. Do not take repeat dose
   c. Consider repeating the dose
   d. None of the above

10. **A local high school student (male) comes into the store to purchase EC. Should you sell him Plan B One-Step?**
   a. Yes, there is no age or gender restriction on the product.
   b. Only after you verify that he is 17 years of age or older.
   c. No, the female planning to use the product must purchase it.
   d. Yes, but you ask him if it is for a female over age 17.

Complete Post Test and Evaluation online at
www.ProCE.com/EC

ProCE, Inc.
848 W. Bartlett Road
Suite 3E
Bartlett, IL 60103
www.ProCE.com