

CLINICAL UPDATE

Emergency Contraception: Are You Confused Yet?

Lydia E Pace, MD, MPH, and Eleanor Bimla Schwarz, MD, MS

Dr. Pace is an instructor of medicine at Harvard Medical School, and Dr. Schwarz is an associate professor of medicine at the University of Pittsburgh.

Emergency contraception (EC) has been a source of heated controversy in the United States for more than a decade. In 2003, after careful review of the scientific evidence, a US Food and Drug Administration (FDA) advisory committee endorsed over-the-counter (OTC) access to levonorgestrel as emergency contraception (EC). Despite the panel's recommendations, the FDA decided instead to place this medication "behind the counter," requiring women facing a contraceptive emergency to either obtain a doctor's prescription or show photo ID proving they were at least 18 years of age. In response to lawsuits, in 2009, a federal judge ruled that at a minimum, EC must be made available without a prescription to all Americans age 17 and over, while further studies that included younger women were reviewed by the FDA. In December 2011, following further review of the data, the FDA again recommended OTC access to Plan B One-Step (one brand of levonorgestrel EC) without age restrictions, and the FDA Commissioner indicated her intent to approve this recommendation. On December 7, however, Kathleen Sebelius took the unprecedented step of overriding the FDA's recommendation and rejecting OTC status for Plan B One-Step.

Amidst the myths and politics, it can be easy to lose sight of the facts that we and our patients need to know. See if you have your EC facts straight by taking the following quiz:

True or False?

1. EC is now available without a prescription in more than 50 countries worldwide.
2. *Plan B* is safer than acetaminophen.
3. *Plan B* is sometimes called RU 486.

4. For effective EC, women need to take two pills 12 hours apart.
5. Studies have shown that increased access to EC increases rates of unprotected intercourse and sexually transmitted infections.
6. *Plan B* only works "the morning after."
7. *ella* (ulipristal acetate) is a newly available EC pill that requires a prescription and is labeled for use up to 5 days after unprotected intercourse.
8. Women should always check a pregnancy test before taking EC.
9. Increased access to EC has not reduced rates of abortion at the population level.
10. A single levonorgestrel pill typically costs \$50.
11. Some US states allow pharmacists to provide EC to women of all ages without a doctor's prescription.
12. One of every three US women has had an induced abortion by the time she reaches age 45.
13. Less than 10% of US women have ever used EC.
14. Women should not use EC more than three times.
15. The Yuzpe regimen (taking multiple OCPs) is as effective as *Plan B*.

Answers

1. True. For example, *Plan B* has been available OTC in Norway since 2000.
2. True. *Plan B* and other EC pills have no serious adverse effects. Known side effects include nausea, vomiting, and disruption of the next menstrual cycle.
3. False. *Plan B* contains levonorgestrel, a progestin that is a component of many commonly used oral contraceptives. RU-486,

now called mifepristone, is an anti-progestin used to terminate pregnancy. In contrast, levonorgestrel works by delaying ovulation and has no effect on an established pregnancy.

4. False. *Plan B One-Step* entails one single levonorgestrel 1.5 mg tablet; *ella* is also a single-dose regimen. Next Choice contains two 0.75 mg tablets taken 12 hours apart. Studies show that a single dose of 1.5 mg levonorgestrel is at least as effective as the two-pill regimen.
5. False. Multiple studies have found that increased access to EC does not increase sexual risk-taking behavior or the prevalence of STI.¹ The "actual use" study cited in the drug manufacturer's application for OTC status provided sexually active women age 15 to 20 with free advance access to EC and found that they used it appropriately.² Teens as young as age 12 have also been shown to have adequate label comprehension.³
6. False. EC is more effective the sooner it is used. However, it has some benefit in preventing undesired pregnancy up to five days after unprotected intercourse.
7. True. Ulipristal is more effective than levonorgestrel, especially for obese women and when more time has elapsed since unprotected intercourse.
8. False. EC prevents pregnancy; a pregnancy test will only be positive after implantation. EC will not disrupt an established pregnancy.
9. True. This seems to be largely due to the fact that unprotected intercourse is very common but

continued on page 2

CLINICAL UPDATE

continued from page 1

that use of EC remains relatively rare. Some women may not recognize that they face risk of undesired pregnancy, some may be uninformed or misinformed about EC, and others may find cost to be a barrier or feel embarrassed by the need to show photo ID.

10. True. *Plan B One Step costs \$35 to \$60; the generic Next Choice is about 10% to 20% cheaper. As most insurance plans do not cover OTC medications, cost remains a significant barrier to access for many women.*
11. True. *Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington State allow pharmacists to provide EC*

pills without a doctor's prescription; however, not all pharmacists in these states have made arrangements to be able to do so.⁴

12. True.
13. True.
14. False. *Other contraceptives are more effective in preventing pregnancy; however, pregnancy poses a greater risk to women's health than repeated use of EC.*
15. False. *Levonorgestrel EC is twice as effective as the Yuzpe regimen.*

Resources on Emergency Contraception

1. Raine TR, Harper CC, Rocca CH, Fischer R, Padian N, Klausner JD, Darney PD. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. *JAMA* 2005; 293:54-62.
2. Wood AJ, Drazen JM, Greene MF. The politics of emergency contraception. *N Engl J Med* 2011.
3. Cremer M, Holland E, Adams B, Klausner D, Nichols S, Ram RS, Alonzo TA. Adolescent comprehension of emergency contraception in New York City. *Obstet Gynecol* 2009; 113:840-4.
4. Kaiser Family Foundation. Women's health policy facts: emergency contraception, 2010. (Accessed December 21, 2011, at www.kff.org.)

SGIM