Over-the-Counter Emergency Contraception: Improved Access for All Ages but Barriers Remain

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Introduction

Access to over-the-counter emergency contraception (EC) has been a highly controversial issue for the last 12 years. In 2001, the Center for Reproductive Rights filed a petition requesting over-the-counter (OTC) access on behalf of over 70 public health and medical organizations. On June 21, 2013, the U.S. Food and Drug Administration (FDA) finally approved Plan B One-Step for OTC sale to women of all ages and it can already be found on some pharmacy shelves. The approval followed a long legal battle and court orders. The allowance of OTC sales will improve access to EC for many women; however, obstacles such as cost and religious or conscientious refusals will still persist.

Background

Currently, a number of levonorgestrel-based EC pills (LNG EC) are approved for sale without prescription to women and men 17 and older. These include Plan B One-Step, Next Choice One Dose, Next Choice and Levonorgestrel Tablets. Ella is another type of EC pill containing ulipristal acetate, but all women must have a prescription to purchase it in the U.S.

On April 5, 2013, federal Judge Edward Korman ordered that LNG EC be made available OTC to women of all ages without a prescription. The judgment allowed the FDA to limit OTC access of two-pill versions if they believed there was significant difference between the one- and two-pill versions. The FDA went on to approve Plan B One-Step, which is a single-pill regimen that is effective in decreasing the chance of pregnancy when taken as soon as possible within three days after unprotected sex. Plan B One-Step will not stop a pregnancy when a woman is already pregnant and there is no medical evidence that the product will harm a developing fetus.

The two-pill version (Plan B) will still require a prescription for women ages 16 and under. Advocates argued that Next Choice One Dose should also be approved by the FDA since it is the generic version of Plan B One-Step. However, on July 22, 2013, the FDA granted market exclusivity to the maker of Plan B One-Step which will extend until April 2016. In the meantime, Plan B One-Step will be the only EC available to women of all ages over-the-counter.

Why should EC be available OTC?

Levonorgestrel EC has been the subject of numerous studies, the findings of which have led to support for OTC availability.

Professional medical organizations support OTC EC

The American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG) and the Society of Adolescent Health and Medicine (SAHM) commended the ruling to allow OTC access without age restriction for Plan B One-Step.¹

EC is not associated with serious side effects

EC is a safe product with no contraindications and very few side effects.² In more than 50 countries, EC has long been available without prescription.³ Repeat use of EC pills does not pose any known health risks, aside from side-effects such as menstrual irregularities.⁴,⁵ Even among women who used EC more than once in the same menstrual cycle, no serious adverse outcomes have been reported.⁶ In fact, because of the health risks that pregnancy carries, taking EC is likely safer than carrying an unwanted pregnancy to term.
EC availability does not increase sexual risk-taking
Better access to EC does not lead to increased sexual risk-taking and offers a back-up method for preventing unintended pregnancy for people who are already using a contraceptive method.7,8 Better access to EC also does not increase acquisition of sexually transmitted infections.9

Women can determine when to use EC and can follow label instructions
Studies show that women and adolescents alike can read and comprehend the EC label and understand when and how to take EC without advice from a health care provider.10,11,12,13,14

Women need timely access to EC
People of all ages have encountered delays and outright denials trying to access EC when age restrictions are in place.15 Many adolescents do not have driver’s licenses or other government-issued forms of photo ID and cannot meet requirements to show such identification. Young women may also receive social messages which discourage them from “planning” to have sex, they may experience sexual coercion, and they may have more difficulty negotiating contraceptive use with partners. Undocumented women also face challenges when asked to provide identification.

U.S. women often use EC as a backup method when other contraception has failed.16 EC pills can be very effective; most estimates suggest that they prevent between 59% and 95% of expected pregnancies.17,18 This means that if 100 women had unprotected sex and then used EC pills, only 1 to 2 of them would become pregnant; if all 100 women had not used EC pills, however, about 8 of them would be expected to become pregnant. EC is generally more effective the sooner it is used. Requiring a prescription makes it more difficult to access EC on weekends and at night, when women are likely to need it.

Recognizing the need to ensure timely access, 17 states and the District of Columbia require emergency rooms to provide information about EC to sexual assault victims. In addition, 13 states and DC require emergency rooms to dispense the drug upon request to sexual assault victims.19

Cost & Religious Refusal Bar Access to EC

Religious refusals & EC
Six states explicitly allow pharmacists to refuse to dispense contraceptives, including EC. Three states allow pharmacies to refuse to dispense EC and the governor of Missouri recently signed a bill shielding pharmacies from requirements to stock specific drugs. However, four states require all pharmacies to fill all valid prescriptions and one state requires all pharmacists to do so.20

Insurance only covers prescription EC
While OTC availability reduces one barrier to EC access, financial barriers may still be a concern. A recent survey by the American Society for Emergency Contraception found that the average price for Plan B One-Step is $48, with generic versions priced on average at $42.21 Insurance coverage of contraception—recently expanded by the Affordable Care Act—will only cover EC if it has been prescribed.22 In some states, pharmacists can dispense EC directly and then bill the insurer.

Nine states allow pharmacists to dispense EC without a physician’s prescription under certain conditions. Seven of these states allow pharmacists to distribute it when acting under a collaborative-practice agreement with a physician; three states, including one that also gives pharmacists the collaborative-practice option, allow pharmacists to distribute EC in accordance with a state-approved protocol.23

Recommendations

Health care providers should offer EC prescriptions to all women in advance. When teens and young women receive advance supplies of EC they do not use the pills repeatedly in place of other contraceptive methods. Moreover, studies show that those who received EC in advance were more likely to use it when needed and to take it within 12 hours after sex, when it is most effective.24,25,26 Offering prescriptions in advance would also enable women who have insurance to cover the costs.

In addition, the FDA should approve generic versions of Plan B One-Step in order to make EC more affordable for women who are unable to obtain a prescription or who do not have insurance.
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References


