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OVER-THE-COUNTER ACCESS TO EMERGENCY CONTRACEPTIVE PILLS

Emergency contraceptive pills (ECPs) offer women a last chance to prevent pregnancy after sex. Because ECPs work by disrupting ovulation, the sooner they are taken the more likely they are to be able to work in the woman's body before ovulation occurs; this is especially true for the most commonly used form of ECP, that containing levonorgestrel.^{1,2} For women who have had sex without contraception, who experience a contraceptive failure, or who have been forced to have sex, timely access to ECPs is crucial. Yet, in many countries around the world, regulatory limitations on the sale of ECPs (including prescription requirements and age restrictions) impede a woman's ability to get ECPs when she urgently needs them.

Restrictions on the sale of levonorgestrel ECPs are medically unnecessary and may present significant barriers that result in an unintended pregnancy; if women are able to access ECPs immediately without restriction, there is a greater chance that they will be able to prevent pregnancy.

This fact sheet addresses only levonorgestrel emergency contraception pills (LNG ECPs), which are the most commonly-available and widely-studied ECPs worldwide.

How are ECPs accessed throughout the world?

Access to ECPs in the pharmacy falls broadly into three categories: over-the-counter (OTC), behind-the-counter (BTC), and prescription-only, although these categories do not precisely describe the situation in each given country. Official regulations and practical realities vary significantly among countries and regions, and even among individual pharmacies and providers. For example, in some settings all products may be held behind the counter in a pharmacy to protect against theft, regardless of the regulatory status of the products sold. In other settings where a prescription is legally required for ECPs, in practical terms it may be possible to purchase the product without a prescription. This factsheet does not provide an exhaustive description of all of the ways in which ECPs are accessed globally, but provides a general overview of the regulatory status of ECPs and a justification for removing restrictions. While clinics, both public and private, are an important access point for ECPs throughout the world, they are not the focus of this factsheet.

Over-the-counter (OTC) sale of a medication means that the product is available at a retail outlet (including convenience stores and grocery stores as well as pharmacies), without the need to consult a health-care provider, pharmacist, pharmacy technician, or clerk. ECPs are officially available OTC in a small handful of countries: Bangladesh, Canada (certain provinces only), Laos, India, and some European countries (including Bulgaria, Denmark, Estonia, the Netherlands, Norway, Portugal, Slovakia, and Sweden). As of August 2013, one brand of ECPs is available OTC in the United States. In 62 countries, ECPs are available **behind-the-counter (BTC)**, which means that no prescription is required, but the product must be held behind the pharmacy counter and the customer must request it from a pharmacist, pharmacy technician or clerk. In more than 100 countries, EC is available **by prescription only**, meaning that unless a woman can obtain ECPs directly from a clinic, she must first get a prescription from a healthcare provider (such as a doctor, midwife, physician assistant or nurse) and then present the prescription at the pharmacy.^{3,4}

In some countries, mechanisms such as collaborative practice agreements and patient group directives have been created to enable pharmacists to directly provide prescription-only medications through partnerships with physicians or other clinical healthcare providers. Such mechanisms authorizing pharmacists to directly provide ECPs exist in some parts of the United States and Canada, as well as the United Kingdom and Australia.⁵⁻⁸

Are LNG ECPs safe enough for OTC access?

Yes, LNG ECPs meet the standard criteria for OTC sale: they have no potential for overdose or addiction, have very low toxicity, are of uniform dosage, have no major drug interactions or contraindications, pose no danger to an existing pregnancy, and the user can determine her own need for the product.⁹⁻¹¹ LNG ECPs have been extensively studied, and have been found to be extremely safe with no need for a clinical exam or pregnancy testing prior to their use.¹² Indeed, LNG ECPs are much safer than many products sold over-the-counter, such as aspirin, which can be fatally toxic if overdosed.¹¹ Side effects following use of ECPs are generally mild and temporary.¹³ LNG ECPs have no contraindications for any woman. LNG ECPs are safe and tolerable when used repeatedly, even within the same menstrual cycle.¹⁴

The latest scientific evidence shows that ECPs work by preventing or inhibiting ovulation, and do not disrupt an existing pregnancy.^{1,2} If a woman who is already pregnant takes LNG ECPs, there are no risks to the pregnancy.^{15,16} Major medical organizations, such as the World Health Organization and the U.S. Centers for Disease Control, agree that LNG ECPs can be taken by a breastfeeding woman with no adverse effects on her infant.^{17,18}

Studies show that women of all ages, including adolescents, can clearly understand the purpose of the medication and its instructions for use, and are able to use it correctly.¹⁹⁻²¹ One objection to increasing access to ECPs has been that it would present a danger to adolescents; this argument was cited in the initial decision not to make ECPs available OTC in the United States. However, the consensus from the medical community, including the Commissioner of the US Food and Drug Administration, the American Academy of Pediatrics, the World Health Organization, and the International Federation of Gynecology and Obstetrics, is that ECPs are absolutely safe and appropriate for adolescents who need them.²²⁻²⁵

For more detail about the safety of levonorgestrel ECPs, please refer to the fact sheet by the World Health Organization and the International Consortium for Emergency Contraception, available at http://www.cecinfo.org/custom-content/uploads/2012/12/WHO_RHR_HRP_10.06_eng.pdf.

Does improved access to ECPs increase the risk of unintended pregnancy and STIs?

Some argue that removing barriers to access ECPs will put women at greater risk of unintended pregnancy and sexually transmitted infections (STIs), citing concerns that women will be less likely to use effective ongoing contraceptives and condoms if ECPs are easily available. However, efforts to increase access to ECPs (such as providing women with EC in advance of need or expanding pharmacist provision through such mechanisms as collaborative practice agreements) have not been shown to increase rates of unintended pregnancy or STIs.²⁶⁻³² The substantial evidence that improving access to ECPs does not lead to adverse outcomes at the population level should be considered by those charged with making public health decisions regarding access to ECPs.

How do restrictions on access to ECPs affect individual women?

Time is of the essence when women need ECPs. Because LNG ECPs do not work if a woman is very close to ovulation, they need to be taken as soon as possible after unprotected sex. When access to ECPs is restricted, these limitations put women at greater risk of unintended pregnancy by delaying the time between unprotected sex and taking ECPs; increasing barriers to access may also discourage women from using ECPs at all due to additional time and financial demands.

Prescription requirements: When a prescription is required to obtain ECPs, a woman must first find a healthcare provider or clinic willing and able to prescribe or provide ECPs (and whom she can afford to pay). If she obtains only the prescription, she must then find a pharmacy that has ECPs in stock, where a pharmacist is available and willing to dispense them.

Keeping ECPs behind the counter: Although pharmacy BTC access is certainly an improvement over prescription-only status, such settings still present barriers. When ECPs are available only behind the counter, the pharmacies' characteristics (such as operating hours, pharmacist workload, privacy concerns, or willingness to provide ECPs) could make the difference between pregnancy and pregnancy prevention. Permitting ECPs to be purchased at a large number of retail outlets with expanded hours would greatly increase accessibility. Each woman is able to assess her own need for ECPs, as having had intercourse is the only indication for using the medication, and as such does not need to consult with a clerk or pharmacy technician unless she has specific questions.

Age restrictions: In a few countries, non-prescription sale of ECPs is restricted to women (and in some cases men) older than 15 to 18 years of age, depending on the country. Younger women must obtain a prescription to purchase ECPs (unless a collaborative practice agreement is in place which allows a pharmacist to directly provide ECPs). These restrictions affect access for women of all ages, as the age restriction necessitates that ECPs must be held behind the counter and that women must provide proof of age.

Recommendation

Removing restrictions on access to ECPs will facilitate women's ability to take them as soon as possible after unprotected or inadequately protected sex. The overwhelming evidence of the safety of LNG ECPs for women of all ages supports the position that there is no reason to restrict or delay women's access to this important contraceptive option. While BTC access is a tremendous improvement over prescription-only sale of LNG ECPs, BTC access may still be a substantial barrier for a woman who has experienced unprotected sex or sexual assault and is in need of ECPs. LNG ECPs are safe enough to be sold without restrictions at pharmacies and any other retail outlet that sells OTC medications, and should not be regulated differently than other OTC medications.



References

- 1 Noe G, Croxatto HB, Maria Salvatierra A, Reyes V, Villarreal C, Munoz C, Morales G, Retamales A. Contraceptive efficacy of emergency contraception with levonorgestrel given before or after ovulation. *Contraception* 2011; 84(5): 486-92.
- 2 Novikova N, Weisberg E, Stanczyk FZ, Croxatto HB, Fraser IS. Effectiveness of levonorgestrel emergency contraception given before or after ovulation — a pilot study. *Contraception* 2007; 75(2): 112-8.
- 3 International Consortium for Emergency Contraception. Emergency contraception status and availability database. 2013; available at: <http://www.cecinfo.org/country-by-country-information/status-availability-database/> Accessed December 9, 2013.
- 4 The Emergency Contraception Website <http://www.not-2-late.com>. Types of emergency contraception. 2013; available at: <http://ec.princeton.edu/worldwide/default.asp#country>. Accessed December 9, 2013.
- 5 Farris KB, Ashwood D, McIntosh J, DiPietro NA, Maderas NM, Landau SC, Swegle J, Solemani O. Preventing unintended pregnancy: Pharmacists' roles in practice and policy via partnerships. *Journal of the American Pharmacists Association* 2010; 50(5): 604-12.
- 6 Soon J, Levine M, Ensom M, Gardner J, Edmondson H, Fielding D. The developing role of pharmacists in patient access to emergency contraception. *Disease Management & Health Outcomes* 2002; 10(10): 601-11.
- 7 Bissell P, Anderson C. Supplying emergency contraception via community pharmacies in the UK: reflections on the experiences of users and providers. *Social Science & Medicine* 2003; 57(12): 2367-78.
- 8 Pharmaceutical Society of Australia. Guidance for provision of a pharmacist only medicine: Levonorgestrel. 2011.
- 9 Sambol NC, Harper C, Kim L, Liu CY, Darney P, Raine TR. Pharmacokinetics of single-dose levonorgestrel in adolescents. *Contraception* 2006; 74(2): 104-9.
- 10 Kook K, Gabelnick H, Duncan G. Pharmacokinetics of levonorgestrel 0.75 mg tablets. *Contraception* 2002; 66(1): 73-6.
- 11 Grimes DA, Raymond E, Scott Jones B. Emergency contraception over-the-counter: the medical and legal imperatives. *Obstetrics & Gynecology* 2001; 98(1): 151-5.
- 12 ACOG practice bulletin. Clinical management guidelines for obstetrician-gynecologists. Number 112, Emergency Contraception. *Obstetrics & Gynecology* 2010; 115(5): 1100-8.
- 13 Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998; 352(9126): 428-33.
- 14 Halpern V, Raymond EG, Lopez LM. Repeated use of pre- and postcoital hormonal contraception for prevention of pregnancy (Review). *Cochrane Database of Systematic Reviews* 2010(1): CD007595.
- 15 De Santis M, Cavaliere AF, Straface G, Carducci B, Caruso A. Failure of the emergency contraceptive levonorgestrel and the risk of adverse effects in pregnancy and on fetal development: an observational cohort study. *Fertility and Sterility* 2005; 84(2): 296-9.
- 16 Zhang L, Chen J, Wang Y, Ren F, Yu W, Cheng L. Pregnancy outcome after levonorgestrel-only emergency contraception failure: a prospective cohort study. *Human Reproduction* 2009; 1(1): 1-7.
- 17 Centers for Disease Control and Prevention. U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. *Morbidity and Mortality Weekly Report* 2010; 59(4): 1-85.
- 18 World Health Organization. Medical eligibility criteria for contraceptive use. Geneva, Switzerland 2010; 4th ed.
- 19 Raymond E, Dalebout S, Camp S. Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product. *Obstetrics & Gynecology* 2002; 100(2): 342-9.
- 20 Raymond EG, L'Engle KL, Tolley EE, Ricciotti N, Arnold MV, Park S. Comprehension of a prototype emergency contraception package label by female adolescents. *Contraception* 2009; 79(3): 199-205.
- 21 Raymond E, Chen P, Dalebout S. "Actual use" study of emergency contraceptive pills provided in a simulated over-the-counter manner. *Obstetrics & Gynecology* 2003; 102(1): 17-23.
- 22 American Academy of Pediatrics Committee On Adolescence. Emergency contraception. *Pediatrics* 2012; 130(6): 1174-82.
- 23 US Food and Drug Administration. Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step. 2011; available at: <http://www.fda.gov/NewsEvents/Newsroom/ucm282805.htm>. Accessed December 9, 2013.
- 24 World Health Organization. Emergency contraception, Fact Sheet No 244. 2012; available at: <http://www.who.int/mediacentre/factsheets/en/>. Accessed December 9, 2013.
- 25 International Consortium for Emergency Contraception and International Federation of Gynecology and Obstetrics. Emergency Contraceptive Pills: Medical and Service Delivery Guidelines. New York, NY 2012; 3rd ed.
- 26 Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *Journal of Pediatric and Adolescent Gynecology* 2004; 17(2): 87-96.
- 27 Raine TR, Harper C, 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. *Journal of the American Medical Association* 2005; 293(1): 54-62.
- 28 Raymond E, Stewart F, Weaver M, Monteith C, Van Der Pol B. Impact of increased access to emergency contraceptive pills: a randomized controlled trial. *Obstetrics & Gynecology* 2006; 108(5): 1098-106.
- 29 Schwarz EB, Gerbert B, Gonzales R. Computer-assisted provision of emergency contraception: a randomized controlled trial. *Journal of General Internal Medicine* 2008; 23(6): 794-9.
- 30 Raymond E, Trussell J, Polis CB. Population effect of increased access to emergency contraceptive pills: a systematic review. *Obstetrics & Gynecology* 2007; 109(1): 181-8.
- 31 Polis CB, Schaffer K, Blanchard K, Glasier A, Harper C, Grimes DA. Advance provision of emergency contraception for pregnancy prevention (full review). *Cochrane Database of Systematic Reviews* 2007(2): CD005497.
- 32 Sander PM, Raymond EG, Weaver MA. Emergency contraceptive use as a marker of future risky sex, pregnancy, and sexually transmitted infection. *American Journal of Obstetrics and Gynecology* 2009; 201(2): 146.e1,146.e6.