International Consortium *for* Emergency Contraception

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EMERGENCY CONTRACEPTION: QUESTIONS AND ANSWERS FOR DECISION-MAKERS

A brief overview of emergency contraception

What is emergency contraception?

The term "emergency contraception" (EC) refers to several contraceptive methods that can be used to prevent pregnancy after sex. These methods include multiple kinds of emergency contraceptive pills (ECPs) as well as insertion of an intrauterine device (IUD).

EC offers women an important second chance to prevent pregnancy when a regular method fails, no method was used, or sex was forced. EC can be used up to 5 days after unprotected sex but is generally more effective the sooner it is used.

Currently the most common EC method, used in most countries around the world, is a special dose of a progestin called levonorgestrel (LNG) in pill form. LNG ECPs are marketed under many names and simply contain higher dosages of the same hormone found in many regular birth control pills. Other types of ECPs approved for use in some countries are ulipristal acetate and low-dose mifepristone.

What is the need for emergency contraception?

All contraceptive methods occasionally fail. Emergency contraception provides an important back-up when routine contraception does not work properly, such as when a condom breaks or pills are missed, or when it is not used at all. Young people in particular may not be prepared for their first sexual experience and may not be using another form of ongoing birth control. For couples who did not use any contraceptive but wish they had, EC also provides a vital second chance to prevent an unwanted pregnancy.

Another critical use for EC is in cases of sexual assault. EC should routinely be offered to sexual assault survivors to prevent the traumatic psychological and physical consequences of rape-related pregnancy.

Emergency contraception's mechanism of action

How do emergency contraceptive pills work?

Emergency contraceptive pills work *before* pregnancy by preventing the release of an egg (ovulation) or by stopping the egg and sperm from meeting. Extensive research on how LNG ECPs, the most commonly used type of EC, work suggests that interference with ovulation is the primary and possibly the only mechanism of action.[1] ECPs do not have *any* effects *after* fertilization.

ECPs *cannot* terminate or interrupt an established pregnancy and will not stop a fertilized egg from implanting in the uterus,[2,3] nor can they harm a developing embryo.[4,5,6] ECPs are ineffective once implantation has begun.

How does EC differ from abortion? Can EC cause an abortion?

ECPs are sometimes confused with medical abortion (sometimes referred to as the "abortion pill"), but the two treatments are very different. **ECPs work after unprotected sex but *before* pregnancy, while medical abortion works *after* pregnancy starts** (once the fertilized egg is implanted in the uterus). Like regular birth control pills, ECPs *prevent* pregnancy, rather than interrupting an established pregnancy.

While ECPs need to be taken within a few days after unprotected sex, medical abortion pills are taken after pregnancy has been established – after a woman misses her period.

Safety and effectiveness of emergency contraception

How safe are emergency contraceptive pills?

ECPs are very safe for all women and girls of reproductive age. Levonorgestrel, the active ingredient in the most common type of ECPs, has been extensively studied and widely used for over 30 years. It is

well-tolerated, is not a known allergen, leaves the body quickly, is not addictive, and has demonstrated no toxic reactions.[7,8,9] LNG ECPs pose no risk of overdose and there are no major drug interactions or contraindications.[9] There have been no reported deaths or serious complications involving ECPs in over three decades of carefully monitored use.

Research also shows that **LNG ECPs have no effect on future fertility**[10,11] and are not associated with increased risk of cancer[12] or ectopic pregnancy.[13] Because ECPs do not contain estrogen, they do not pose any risk of stroke or venous thromboembolism.

Can EC pills harm a fetus or cause birth defects if taken by a woman who is already pregnant?

ECPs will not harm a fetus if a woman is already pregnant, nor will they cause birth defects if the pills fail to prevent pregnancy.[4,5,6] If ECPs are taken after a pregnancy has been established, they are simply ineffective and have *no harmful effects* on either the woman or the fetus.

How effective is emergency contraception?

EC can be effective up to five days after unprotected sex, but it is generally more effective the sooner it is used. Most efficacy estimates for LNG ECPs suggest that they prevent between 59% and 95% of expected pregnancies.[14,15] In real life terms, that means that if 100 women had unprotected intercourse and then used LNG ECPs, only 1 to 2 of them would become pregnant; if all 100 women had not used LNG ECPS, however, about 8 of them would be expected to become pregnant.

Other types of ECPs (ulipristal acetate and mifepristone) are at least as efficacious as LNG ECPs, and potentially more so.[16,17] Emergency insertion of an IUD is even more effective.[18]

What happens if a woman takes EC pills more than once?

Repeat use of ECPs does not pose any known health risks.[19,20] ECPs **remain safe and effective** in preventing unwanted pregnancy over multiple uses (although using a regular, ongoing method is recommended as the most effective way to prevent pregnancy). Even among women who used ECPs more than once in the same menstrual cycle, no serious adverse outcomes were reported.[21] Because of the health risks that pregnancy carries, **taking ECPs is likely safer than carrying an unwanted pregnancy to term.** As such, women should not be limited in the frequency or number of times they can access ECPs.

The World Health Organization's 2012 fact sheet on EC states that ECPs' "repeated use poses no known health risks," aside from side-effects such as menstrual irregularities (although it recommends against regular use of ECPs as an ongoing contraceptive method because other methods are more effective).[19] Earlier WHO guidelines on ECP service delivery further state that health risks of repeated use of ECPs "should never be cited as a reason for denying women access to treatment."[22]

Professional support for emergency contraception

What do established medical and other health-related associations say about EC?

Leading health-related professional associations and organizations around the world support emergency contraception, including the World Health Organization (WHO),[19] the International Federation of Gynecology and Obstetrics (FIGO),[23] the United Nations Population Fund (UNFPA),[24] and the American Academy of Pediatrics (AAP).[25] Their endorsements of EC reflect confidence not only in EC's safety and efficacy, but also in the belief that greater access to EC is vital.

Legal status and availability of emergency contraception

Is emergency contraception legal and available in my country?

Levonorgestrel emergency contraceptive pills are registered for sales and distribution in over 140 countries. Even in countries where no dedicated product has been registered, EC may sometimes be supplied with a special import license, and women can always use a higher dose of regular birth control pills for EC.[26] To learn more about the status of EC in your country, see www.emergencycontraception.com.

Other concerns about emergency contraception

Should emergency contraceptive pills be provided over-the-counter?

ECPs are safe and appropriate for over-the-counter (OTC) purchase by all women and adolescents. OTC access is particularly critical because ECPs are more effective the sooner they are taken after unprotected intercourse. Requiring a prescription for ECPs often forces women to make two trips: one to a clinic to get the prescription and a second to a pharmacist to fill the prescription. This **delays the process**

and presents a significant barrier for women who lack access to transportation or who live in rural areas without easy access to doctors or pharmacies. Moreover, requiring a prescription makes **access to ECPs on weekends and at night** (when many contraceptive mishaps occur) more difficult.

Studies show that **women and teens alike can read and comprehend the ECP label and understand when and how to take ECPs without advice from a health care provider.**[27,28,29,30,31] Many national and international agencies recommend non-prescription access to EC. In countries where ECPs remain prescription-only, providers may consider offering advance prescription or provision.

Will access to emergency contraception encourage riskier sexual activity, such as:

- increased risk of pregnancy or STIs?
- increased frequency of unprotected sexual intercourse?
- decreased use of condoms or ongoing birth control methods?

There is no evidence to suggest that emergency contraception leads to increased risk of pregnancy or contraction of sexually transmitted infections (STIs), nor to any increased sexual or contraceptive risk-taking behavior. In order to approximate whether taking EC increases risky sexual behavior, several studies have compared women who receive advance provision of ECPs (and who, in turn, often use EC at a higher-than-average rate) against women who do not receive advance provision of EC.[32] The studies have found that the women who received advance provision of EC were no different from those who did not in regard to frequency of unprotected intercourse,[32] use of more effective methods of contraception,[32] or use of condoms.[32]

Some of these studies focused specifically on younger women[33,34,35,36] and have shown that **enhancing access to LNG ECPs does not increase sexual or contraceptive risk-taking behavior in youth.** When teens and young women receive advance supplies of LNG ECPs, they do not use the pills repeatedly in place of routine contraceptive methods.[33,35,37] Moreover, those who received LNG ECPs in advance were more likely to use it when needed and to take it within 12 hours after sex, when it is most effective.[33,35,37]

Can and should teens and young women have access to EC?

Emergency contraception is a safe and important option for young women.[7] While abstinence is a reliable way to prevent pregnancy and STIs, the reality is that **the majority of people become sexually active by age 20.** While not all young people are sexually active, in many cases those who are do not use regular contraceptive methods, as **young women often lack information about and access to ongoing family planning methods and services.**[38,39] Unfortunately, young women also face social mores that discourage them from "planning" to have sex, **experience sexual coercion,** and have difficulty negotiating contraceptive use. For many adolescent girls, protection against pregnancy can be a matter of life and death, as **complications from adolescent pregnancy and childbirth are a leading cause of death among adolescent girls ages 15-19** in low- and middle-income countries.[40] These factors make EC a particularly critical option for young women by offering them a valuable second chance to avoid an unplanned pregnancy.

EC is safe for young women, with no contraindications and minimal side effects, and **teens are able to understand EC product labeling.**[28,29,30] Moreover, ample evidence shows that **improving access to EC among young women does not lead to higher rates of STIs or unintended pregnancies,**[32] or increase risk-taking behavior.

Increasing access to emergency contraception

How can my country increase women's access to EC?

- **Register additional EC products** (for countries that have few or no dedicated EC products).
- Include EC in country-level **essential medicines lists** and national **family planning guidelines.**
- Ensure that EC is included in country **guidelines on post-rape care.**
- Encourage pharmacy access by making EC available **over the counter without age restrictions.**
- Include EC in **public sector procurement** and supply systems.
- Where appropriate, incorporate **community-based distribution** of EC into national protocols.
- Track and **reduce provider stock-out** of EC.
- Ensure that national-level professional bodies, including pharmacy associations, provide **clear guidance on EC provision** to their members.
- Ensure that EC is **included in pre-service provider training and ongoing professional development** for pharmacists, doctors, nurses, and midwives.
- Promote **public education** of EC to increase consumer-level knowledge.
- Ensure that **women at all income levels** can afford EC.
- **Address poor quality and counterfeit EC** products where they exist.

References

1. International Consortium for Emergency Contraception (ICEC) and International Federation of Gynecology & Obstetrics (FIGO). How do levonorgestrel-only emergency contraceptive pills (LNG ECPs) prevent pregnancy? Statement on mechanism of action. March 2012 (http:// www.cecinfo.org/publications/policy.htm, accessed 23 October 2012).
2. Noe G, Croxatto H, Salvatierra AM, Reyes V, Villarroel C, Munoz C, Morales G, Retamales A. Contraceptive efficacy of emergency contraception with levonorgestrel given before or after ovulation. Contraception 2011;84:486-492.
3. 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):112-118.
4. 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.
5. 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;24(7):1605-11.
6. World Health Organization. Fact sheet on the safety of levonorgestrel-alone emergency contraceptive pills (LNG ECPs). June 2010 (http://whqlibdoc.who.int/hq/2010/WHO_RHR_HRP_10.06_eng.pdf, accessed 23 October 2012).
7. Sambol NC, Harper CC, Kim L, Liu CY, Darney P, Raine TR. Pharmacokinetics of single dose levonorgestrel in adolescents. Contraception 2006;74(2):104-109.
8. Kook K, Gabelnick H, Duncan G. Pharmacokinetics of levonorgestrel 0.75 mg tablets. Contraception 2002;66(1): 73-76.
9. Grimes DA, Raymond EG, Scott Jones B. Emergency contraception over-the-counter: The medical and legal imperatives. Obstetrics and Gynecology 2001;98(1):151-155.
10. Norris Turner A, Ellertson C. How safe is emergency contraception? Drug Safety 2002;25:695-706.
11. Liskin L, Rutledge AH. After contraception: Dispelling rumors about later childbearing. Population Reports. Series J: Family Planning Programs 1984;(28):J697-731.
12. American College of Obstetricians and Gynecologists. Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists, Number 69: Emergency Contraception. Obstetrics and Gynecology 2005;106:1443-1452.
13. Cleland K, Raymond E, Trussell J, Cheng L, Zhu H. Ectopic pregnancy and emergency contraceptive pills: a systematic review. Obstetrics and Gynecology 2010;115(6):1263-6.
14. Trussell J. Understanding contraceptive failure. Best Practice and Research Clinical Obstetrics and Gynaecology. 2009;23:199-209.
15. Dada OA, Godfrey EM, Piaggio G, von Hertzen H. A randomized, double-blind, noninferiority study to compare two regimens of levonorgestrel for emergency contraception in Nigeria. Contraception. 2010;82:373-378.
16. Cheng L, Gulmezoglu AM, Piaggio G, Ezcurra E, Van Look PF. Interventions for emergency contraception. Cochrane Database of Systematic Reviews 2008;(2):CD001324.
17. Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet. 2010;375:555-562.
18. International Consortium for Emergency Contraception. The Intrauterine Device for Emergency Contraception. September 2012 (http://www.cecinfo.org/custom-content/uploads/2012/12/IUD_FactSheet_2012.pdf, accessed 23 January 2013).
19. World Health Organization. Emergency contraception fact sheet No. 244. July 2012 (http://www.who.int/mediacentre/factsheets/fs244/en/index.html, accessed 5 February 2013).
20. International Consortium for Emergency Contraception Repeated use of emergency contraception: the facts. July 2003 (http://www.cecinfo.org/publications/PDFs/policy/RepeatedUse_English.pdf, accessed 2 March 2010).
21. Halpern V, Raymond EG, Lopez LM. Repeated use of pre- and post-coital hormonal contraception for prevention of pregnancy. Cochrane Database of Systematic Reviews 2010;(1):CD007595.
22. World Health Organization. Emergency Contraception: A guide for service delivery. 1998 (http://apps.who.int/iris/bitstream/10665/64123/1/WHO_FRH_FPP_98.19.pdf, accessed 5 February 2013).
23. International Federation of Gynecology and Obstetrics Committee for the Ethical Aspects of Human Reproduction and Women's Health. Recommendations On Ethical Issues In Obstetrics And Gynecology. November 2003.
24. United Nations Population Fund Frequently Asked Questions. November 2008, from http://www.unfpa.org/public/about/faqs.
25. American Academy of Pediatrics. Policy Statement: Emergency Contraception. 26 November, 2012 (http://pediatrics.aappublications.org/content/130/6/1174).
26. Association of Reproductive Health Professionals. Clinical Proceedings: Update on Emergency Contraception. March 2011 (http://www.arhp.org/Publications-and-Resources/Clinical-Proceedings/EC/Methods, accessed 5 February 2013).
27. Raymond EG, Dalebout SM, Camp SI. Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product. Obstetrics and Gynecology 2002;100(2):342-9.
28. Raine TR, Ricciotti N, Sokoloff A, Brown BA, Hummel A, Harper CC. An over-the-counter simulation study of a single-tablet emergency contraceptive in young females. Obstetrics and Gynecology 2012;119(4):772-9.
29. 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.
30. Cremer M, Holland E, Adams B, Klausner D, Nichols S, Ram RS, Alonzo TA. Adolescent comprehension of emergency contraception in New York City. Obstetrics and Gynecology 2009;113(4):840-4.
31. Glasier A, Baird D. The effects of self-administering emergency contraception. New England Journal of Medicine 1998;339(1):1-4.
32. Polis CB, Schaffer K, Blanchard K, Glasier A, Harper CC, Grimes DA. Advance provision of emergency contraception for pregnancy prevention: a meta-analysis. Obstetrics and Gynecology 2007;110(6): 1379-88.
33. 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.
34. Stewart HE, Gold MA, Parker AM. The impact of using emergency contraception on reproductive health outcomes: A retrospective review in an urban adolescent clinic. Journal of Pediatric and Adolescent Gynecology 2003;16(5):313-318.
35. Harper CC, Cheong M, Rocca CH, Darney PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. Obstetrics and Gynecology 2005;106(3):481-491.
36. Belzer M, Sanchez K, Olson J, Jacobs AM, Tucker D. Advance supply of emergency contraception: a randomized trial in adolescent mothers. Journal of Pediatric and Adolescent Gynecology 2005;18(5):347-54.
37. Raine TR, Harper CC, Rocca CH, Fischer R, Padian N, Klausner JD, Darner 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):55-62.
38. Weiss DC, Harper CC, Speidel JJ, Raine TR. Should Teens Be Denied Equal Access to Emergency Contraception? Bixby Center for Global Reproductive Health, University of California, San Francisco 2008.
39. Mosher WD, Jones J. Use of contraception in the United States: 1982–2008. Vital and Health Statistics, Series 23: Data from the National Survey of Family Growth 2010;(29):1-44.
40. World Health Organization. Adolescent pregnancy fact sheet No. 3644. May 2012 (http://www.who.int/mediacentre/factsheets/fs364/en/index.html, accessed 5 February 2013).