

Information for Policy Makers

Objective

To develop a policy environment—both political and social—supporting the introduction and broad programming of emergency contraceptive pills (ECPs).

This module provides information that will help advocates work with key political leaders, government officials, and other stakeholders in the health and family planning community to facilitate provision of an ECP product and related services. The following topics are discussed:

- Political Context
- Resources
- Key Audiences
- Key Messages
- Mexico City Policy and Emergency Contraception
- Domestic Violence, Rape, and Emergency Contraception
- Choosing Effective Channels to Communicate Messages
- Local Data Illustrating Need for Emergency Contraception

Module A: Information for Policy Makers, Module C: Raising Public Awareness, and Module D: Informing Clients, are closely related. Ideally, ECP access will involve all the areas discussed in these three modules—policy, public awareness, and informing clients. Each module provides resources, tools, and techniques that can be adapted according to the target audience and the environment.

Tools Provided at the End of This Module

Statements on ECPs by International Organizations, Agencies, and Major Donors of Contraceptive Commodities:

- American College of Obstetricians and Gynecologists (ACOG) News Release (February 2001).
- International Consortium for Emergency Contraception (ICEC) Evidence-Based Policy Statements (July 2003).
- International Federation of Gynecology and Obstetrics (FIGO) Ethics Committee Report: Guidelines in Emergency Contraception. *International Journal of Gynecology & Obstetrics* 77:71-175 (2002).
- International Planned Parenthood Federation (IPPF). International Medical Advisory Panel (IMAP) Statement on Emergency Contraception. (October 2003).

Tools continued...

- United Nations Population Fund (UNPFA) Statement on Emergency Contraception (2003).
- United States Agency for International Development (USAID) Statement on Emergency Contraception (2003).
- World Health Organization (WHO) Statement on Emergency Contraception. Fact Sheet No. 244 (June 2000).

Resources for Developing Messages for Policy Makers

- Annotated Bibliography of Core Evidence-Based Research on Emergency Contraception
- Key Facts About Emergency Contraception

Political Context

Government support (whether explicit or implicit) is a prerequisite for successfully integrating ECPs into a large-scale program. The collaboration of government agencies such as the ministry of health and the drug regulatory agency is critical to ensure the availability of an ECP product and appropriate service provision. Although government support is essential, it can be difficult to obtain, due to strong political pressures—and lack of support presents serious barriers. For example, in one country, registration of a dedicated ECP product was delayed over five years because government approval was contingent on the approval of religious leaders. In other countries where abortion is a major political issue, political leaders have been reluctant to become involved with provision of ECPs through government-funded programs. Because navigating such environments can be difficult, it is essential to understand the political currents and how they relate to family planning, before initiating ECP integration.

Resources

The availability of resources to build support in a given environment is another important consideration. Some strategies for influencing policy can be very costly; others, such as holding workshops and meeting with representatives, can be fairly low-cost. In considering the financial, as well as the human, resources that will be involved, the following questions can be useful in helping to determine the direction the strategy should take.

- Is the current political environment favorable toward family planning and reproductive health services?
- What are the social, cultural, or religious attitudes toward family planning?
- What are the reproductive health issues that raise concern among political leaders?
- From what types of leaders is it most critical to gain support?
- What are the potential sources of financial support for providing information to policy makers and stakeholders, and how much effort will be needed to secure that support?
- Are there organizational resources to undertake a large-scale effort to generate ECP support, or should a smaller, more focused campaign be considered?

Harnessing resources available for incorporating ECPs into family planning programs can be a challenge. In some countries, like Mexico, foundation donors were integral to providing substantial funding for the large-scale advocacy campaign undertaken there. In many places, however, this type of funding may be difficult to access, and it is important to be aware of other support available and the mechanisms through which it can be obtained.

There are different types of resources or organizations that may be interested in contributing to efforts to integrate ECPs into public-sector programs. In some settings government may be able to make ECPs part of the country's method mix and integrate ECP information into ongoing client outreach and provider training. Bilateral donors or multilateral donors, particularly those who provide contraceptives or support reproductive health activities, can be a resource. This support is most effectively sought at the country-level mission or country office engaged in health and/or reproductive health work. Private foundations or local donors supportive of reproductive health may have interest in supporting activities related to ECP integration. Include these potential donors early in the planning stages to assess their interest and find out what they can or cannot support.

Key Audiences

When resources requirements and availability are known, the next step is to identify the stakeholders and policy makers whose support is needed. In several countries that have successfully integrated ECPs into large programs, these were individuals from the health care sector including government, international aid agencies, and professional medical groups. Questions that will help identify the target audiences include:

- Who are the key policy makers and stakeholders in the health and family planning community?
- Who contributes to decisions about contraceptive method mix?
- Among these policy makers and stakeholders, which ones are likely or unlikely to support ECP mainstreaming efforts?
- Who are the cultural or religious leaders that might oppose or support increasing access to ECPs?
- What other groups or individuals influence policy related to health and family planning, and which of them could provide support?

Examples of stakeholders in the provision of ECPs include:

Key Audiences	Examples of Organizations
Decision makers and program planners at national and local levels	<ul style="list-style-type: none"> • Ministry of health <ul style="list-style-type: none"> – National family planning program – National maternal and child health division • Ministry of justice • Health insurance programs • Representatives from multilateral and bilateral donor agencies
Local leaders	<ul style="list-style-type: none"> • Community • Local health groups • Women's groups • Religious leaders • Domestic violence support groups • Police and local law officers
Professional groups	<ul style="list-style-type: none"> • Medical associations and societies • Medical education institutions • Pharmacists associations • Research councils and institutes
Pre-service academic institutions	<ul style="list-style-type: none"> • Medical schools • Nursing schools • Pharmacy schools
Providers	<ul style="list-style-type: none"> • Directors of hospitals and clinics • Clinic health workers • Safe abortion service providers • Midwives/traditional birth attendants

ECP forum for stakeholders

In cases where multiple stakeholders are involved, it is important to create mechanisms for communication and collaboration among them. Creating a forum where individuals from these groups can facilitate effective collaboration, avoid duplication, and maintain momentum of advocacy efforts is important. Forums can sort out issues and look at ECP introduction from a variety of perspectives. These forums can serve as a mechanism through which to address issues around emergency contraception, increase the number of people receiving accurate messages about ECPs, and gain the attention of and support from important stakeholders. In several countries this has been a key factor in the successful introduction of ECPs, and this approach should be applied wherever possible when advocating for wide access to ECPs.

Lessons Learned

Holding a National Consensus Forum in India

In cooperation with several organizations, the Consortium on National Consensus for emergency contraception in India held a two-day forum on emergency contraception. The main objectives of the forum were to present updates on the latest advances in emergency contraception, to discuss and debate the strategies for ECP introduction, and to set forth guidelines for introducing emergency contraception in India. Participants included a host of international and national technical experts, policy makers, researchers, pharmaceutical companies, women's advocates, legal experts, nongovernmental organizations, professional bodies, and service providers. The first day of the forum consisted of five sessions during which leading experts addressed the main issues, current data, and findings from other countries where ECPs are already integrated. During the second day, an expert forum was held on six key issues related to ECP introduction in India. A consensus on how to move forward with respect to each of the areas was reached and adopted. The main issues on which a consensus was reached were: selection of a dedicated method for EC in India, preintroduction of media campaigns for public awareness, training curriculum for health care providers, ideal approach to broad-scale introduction and distribution of ECPs, and client information and counseling for safe use. The National Consensus Forum, which occurred in 2002, helped pave the way for introduction of emergency contraception in India. Information on this forum has been compiled in the *The Report & Recommendations of National Consensus of Consortium*, which can be accessed online at <http://www.ecindia.org/report.htm>.

Including a Range of Interests Helps Garner Support for Emergency Contraception in Zambia

In Zambia, ECP advocates invited a group of individuals representing a wide range of organizations to participate in discussions and meetings on issues related to emergency contraception. Leaders from women's groups, the Catholic Church, the Ministry of Health, and other groups were invited to participate in a discussion about the results of an ECP study conducted by the Population Council. The focused discussions around this study helped highlight evidence about ECPs and simultaneously informed groups on all sides of the issue about emergency contraception. It proved to be a very effective way to build consensus on the issues surrounding the local introduction of ECPs in Zambia. This study is included in the annotated bibliography in the tools section of this module (Skibiak et al. 1999).

Key Messages

Once audiences have been identified, the next step is to determine what information can most effectively inform their decisions and garner their support. In planning key messages and strategies, it is critical to draw from evidence-based and published information about emergency contraception, including why it is a public health issue and the benefits of integrating it into a family planning program. Provision of correct information helps address common misperceptions about ECPs that are often the cause of controversy. Recent research on ECPs has resulted in an excellent body of widely published studies with information on issues such as ECPs mechanism of action, safety, and efficacy—issues that are frequently brought up for discussion. The following section has been designed to provide succinct information on important topics and questions that often arise among policy makers. Links to articles and resources that can be used in developing program-specific messages and information dissemination strategies are provided. Many of the articles and resources listed below are included in the annotated bibliography, which is located in the tools section. The bibliography also contains additional resources that may be useful in developing messages.

ECPs are safe

ECPs are both safe and effective for women to use.^{1,2}

Both the United States Food and Drug Administration (FDA) and the World Health Organization (WHO) have stated that ECPs are safe for use.

- Researchers often extrapolate data from safety studies conducted on oral contraceptive pills (OCPs) taken daily over a long period of time for regular contraception to demonstrate that ECPs are safe.³ Because ECPs are taken for a very short period of time, researchers have concluded in reviews of published data on OCPs and ECPs, that the contraindications for use of daily oral contraception are not applicable to ECPs.⁴
- In the 13-year period following the availability of the dedicated Yuzpe (also known as the estrogen-progestin, or combined) regimen product in Great Britain, the regimen was used over 4 million times. Medical reports showed no clear evidence directly linking adverse events with use of the Yuzpe regimen.⁵
- WHO has stated that there are no contraindications to ECPs due to the small overall hormone dose and short duration of use.⁶
- The only condition restricting use of ECPs is an established pregnancy, defined as beginning with implantation, not because ECPs are harmful, but because they will not work if a woman is already pregnant. Researchers have concluded that ECPs taken inadvertently during pregnancy will not harm a developing fetus. These conclusions are based on studies of oral contraceptive pills, including high-dose formulations, that show oral contraceptives pose no risk of birth defects.^{4,7,8,9,10,11,12}
- Because ECPs have been shown to be safe and effective, many countries have simplified access by making them available without prescription or directly from a pharmacist. ECPs are available direct from a pharmacist in Albania, Belgium, Benin, Cameroon, Congo, Denmark, Finland, France, Gabon, Guinea-Bissau, Israel, Ivory Coast, Lithuania, Madagascar, Mali, Mauritius, Namibia, Portugal, Senegal, South Africa, Sri Lanka,

Switzerland, Thailand, Togo, Tunisia, United Kingdom, and parts of United States and Canada. They are available over-the-counter in Norway and Sweden.¹³ In 2003 an FDA review panel recommended that progestin-only ECPs be available over-the-counter in the United States.

ECPs are effective

The effectiveness of ECPs varies, depending on the regimen and how soon after sex they are taken.

- There are two major types of ECPs on the market today: the levonorgestrel-only (also known as progestin-only) regimen and the Yuzpe (or combined estrogen and progestin) regimen. The levonorgestrel-only regimen has fewer side effects and is more effective.
- On average, if 100 women have unprotected intercourse during the time of the month when they are most fertile, 8 will become pregnant. If they all took the levonorgestrel-only ECP regimen, 1 would be expected to become pregnant (an 89 percent reduction in pregnancy risk).^{*} If all of those women used the Yuzpe regimen, 2 would be expected to become pregnant (a 75 percent reduction in pregnancy risk).^{2*}
- The sooner after unprotected intercourse a woman takes ECPs, the lower her risk of pregnancy. ECPs will be most effective if taken within 24 hours; the effectiveness diminishes with each day, up to 120 hours (5 days).^{2,14,15,16}

Mechanism of action of ECPs

- ECPs are effective only before a pregnancy is established (clinically defined as implantation of a fertilized egg in the lining of the uterus).^{**} They cannot work after a fertilized egg has been implanted.¹⁷
- ECPs' primary mechanism of action is the inhibition or delay of ovulation.^{18,19,20,21,22,23,24,25,26}
- Besides inhibiting or delaying ovulation, there is no unequivocal clinical evidence for other mechanisms of action although ECPs may work by:
 - Inhibiting fertilization through thickening of the cervical mucus resulting in trapping of sperm or alterations in the tubal transport of sperm or egg—but no data exist to confirm this possible mechanism of action.^{27,28,29}
 - Impairing endometrial receptivity to implantation of a fertilized egg.^{21,30,31,32,33,34} However, the evidence showing endometrial effects of ECP treatment is mixed, and it is not clear that the endometrial changes would inhibit implantation.^{19,22,35,36}
- Timing plays a key role in how ECPs work. Studies have shown that the specific mechanism of action and effectiveness of ECPs may depend on:
 - Cycle day on which intercourse occurred.
 - Cycle day on which treatment is used.^{19,20,22,30,37,38}

^{*}These estimates of reduction in the risk of pregnancy following ECP use are based on studies that evaluated ECP use within a 72-hour time frame.

^{**}Individuals have their own interpretations of when a pregnancy begins. The definition above is provided within a medical/clinical context.

For more information on the mechanism of action of ECPs, refer to the International Consortium for Emergency Contraception's statement on mechanism of action in the tools section of this module.

ECPs can help reduce the number of abortions

Research suggests that access to ECPs can reduce the number of abortions that occur each year.

- It is estimated that in the United States in 2000, 51,000 pregnancies that would have resulted in abortions were prevented by the use of ECPs.³⁹
- In a Chinese study, researchers estimated that nearly half (47%) of the abortions in Shanghai could have been prevented if combined-regimen (Yuzpe method) ECPs had been available to women.⁴⁰

Most evidence suggests that advance provision of ECPs does not negatively affect regular, ongoing contraceptive use

- Most research suggests that advance provision of ECPs does not negatively affect regular contraceptive use.^{41,42,43,44}
- A Scottish study showed that women did not stop using other more effective contraceptive methods when a back-up method such as ECPs was available in advance.⁴¹
- Another study showed that women did not abandon regular use of condoms for pregnancy and disease protection, which would have increased their risk of sexually transmitted infection (STI) and HIV. The study concluded that couples may feel more confident about relying on condoms if emergency contraception is available as a backup method.⁴³
- A study conducted in Zambia, however, provided some evidence that advance provision of ECPs may have encouraged nonuse of regular family planning methods among users for reasons such as coercion by spouse, curiosity about the method, confidence in ECP effectiveness given its higher dosage compared to regular oral contraceptives, and preference for the convenience of ECPs. Despite this, researchers still concluded that advance provision of ECPs to women is an important option and that issues pertaining to the use of ECPs and other family planning methods can be overcome with provider training and user education.⁴⁵

Medical providers should emphasize continued condom use for clients at risk of STIs, with emergency contraception as a backup.*

Effectiveness of ECPs is increased by advance provision

- Women who received ECPs in advance of need were more likely to use them when needed than those who did not have a supply at home.⁴¹

* A model for a dual protection approach (an approach that promotes strategies that prevent both unwanted pregnancy and STI/HIV infection) is provided by the National Contraception Policy Guidelines issued by the Republic of South Africa's Department of Health. In discussing barrier methods, these guidelines state, "In the event of condom failure, access to emergency contraception should be promoted more extensively." National Contraception Policy Guidelines Within a Reproductive Health Framework. Republic of South Africa, Department of Health (2001). <http://www.doh.gov.za/docs/factsheets/guidelines/contraception/contraception01.pdf>. <http://www.doh.gov.za/docs/factsheets/guidelines/contraception/contraception02.pdf>.

- Women who have ECPs in advance of need will most likely use them sooner after unprotected intercourse, which increases the effectiveness of this method.^{42,46}
- The effectiveness of ECPs decreases significantly the longer a woman waits after intercourse to take them. Advance provision is an important option because it reduces barriers to timely access.¹⁴

For more information on the timing of ECPs and effectiveness, see the International Consortium for Emergency Contraception's statement on regimen in the tools section of this module.

Access to ECPs does not cause promiscuity among adolescents

The concern is frequently voiced that access to ECPs will cause promiscuity among youth. Two recent studies provided evidence that information about and access to contraceptive methods, including ECPs, does not lead to promiscuity or earlier initiation of sex among adolescents.^{47,48}

Repeat use of ECPs does not pose health risks

- Repeat use of ECPs poses no health risks, according to WHO, which has placed repeated ECP use in Category 1 of its medical eligibility guidelines, indicating that there is no restriction for the repeated use of this contraceptive method.⁶
- Experience with ECPs suggests that repeat use within the same cycle is uncommon.⁴¹ Use of levonorgestrel-only ECPs as frequently as four times a month did not reveal negative health risks.⁴⁹ While repeat use is not a reason to deny a woman access to ECPs, it is an indication that a woman needs further counseling on routine contraceptive methods, as most other methods are more effective for regular use.⁶ Women who have regular intercourse (more than four times per month) are not advised to use ECPs as a regular contraceptive method because they are not as effective as regular contraception.⁶

For more information on repeat use, see the International Consortium for Emergency Contraception's statement on repeat use of emergency contraception in the tools section of this module.

Mexico City Policy and Emergency Contraception

Emergency contraception, like other methods of contraception, is not subject to U.S. government restrictions on development funds that apply to abortion services, counseling and referral, or lobbying. This has been a point of confusion. Foreign governments and nongovernmental organizations that receive U.S. development assistance may provide emergency contraception services, information, and referral. For more information see the Population Action International (PAI) publication, "Emergency Contraception and the Global Gag Rule—An Unofficial Guide," which provides information and clarity about the Mexico City Policy. It can be accessed at the PAI website: http://www.populationaction.org/resources/publications/globalgagrule/GagRule_download.htm.

Domestic Violence, Rape, and Emergency Contraception

Gender-based violence is a significant problem worldwide. It can include physical, sexual, psychological, and economic abuse of women. A review of almost 50 population-based surveys found that between 10 and 50 percent of women report being hit or otherwise physically harmed by an intimate male partner at some point in their lives.⁵⁰ This violence can have serious health consequences for women, especially in terms of their reproductive and sexual health. For women who are affected by violence, emergency contraception is particularly important. Women who have been sexually abused are much more likely than nonabused women to use family planning clandestinely; they also are more likely to have had their partner stop them from using family planning and to have had a partner refuse condom use to prevent disease.⁵⁰ Rape survivors are also at risk of unintended pregnancy, but because many women in this situation never seek medical care where information about ECPs can be provided, it is important that they be reached through other advocacy avenues. Including those groups and individuals who assist sexual abuse and rape survivors, such as police and local law officers, in advocacy campaigns and trainings is an important aspect of ensuring ECPs reach women who need them.

The Pacific Institute for Women's Health (PIWH), has been working to improve rape and domestic violence survivors' knowledge about and access to ECPs through partnerships with local organizations in Latin America. PIWH found that community-based health care providers participating in a series of workshops conducted in several Latin American countries all had assisted women who had been sexually assaulted or were living with domestic violence, highlighting the severity of the issue in many communities. Following such a workshop, the Organización Lilita de Mujeres Independientes in Mexico worked to train Tijuana Secretary of Health personnel on ECP service provision. PIWH has also worked with organizations in Baja California and Planned Parenthood in San Diego to raise awareness about emergency contraception and advocate for the inclusion of emergency contraception in the family planning norms of the Mexican Ministry of Health. More information on PIWH's work with emergency contraception can be found in Module C: Raising Public Awareness and on PIWH's website: <http://www.piwh.org/latinamerica.html>.

Choosing Effective Channels to Communicate Messages

Once the key messages have been identified, select the most effective channels for reaching the intended audiences. The following questions can help in considering which communication channels to use.

- What type of information dissemination activities would be most effective in the current environment?
- What are the most important points that need to be made?
- How can these points be made so they have maximum impact on the intended audience?

Local Data Illustrating Need for Emergency Contraception

Specific local data can significantly strengthen the argument for making ECPs widely available in a country. Data on serious health, poverty reduction, and social problems that can be positively affected by decreasing the number of unintended pregnancies and abortions can be powerful tools in advocating policy change to support access to ECPs. Useful data include:

- Adolescent pregnancy rates.
- Unintended pregnancy rates.
- Abortion rates and sequelae.
- Government expenditures on unintended pregnancy and abortion or postabortion care.
- Birth spacing statistics.

Country-specific data for over 220 countries can be found on the Internet at the Population Reference Bureau website, <http://www.prb.org>, which has links to additional data resources, Measure and PopNet. Another resource is the Global Health Council website, <http://globalhealth.org>. Useful data for ECP information dissemination can be accessed at <http://www.globalhealth.org/news/article/2319>.

References

- ¹Ho, P.C. and Kwan, M.S. A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in post-coital contraception. *Human Reproduction* 8(3):389-392 (1993).
- ²WHO 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* 352(9126):428-433 (1998).
- ³Glasier, A. Safety of emergency contraception. *Journal of American Medical Women's Association* 53(5 Suppl 2):219-221 (1998).
- ⁴Norris Turner, A. and Ellertson, C. How safe is emergency contraception? *Drug Safety* 25(10):695-706 (2002).
- ⁵Glasier, A. Emergency postcoital contraception. *New England Journal of Medicine* 337(15):1058-1064 (1997).
- ⁶World Health Organization. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. 2nd ed. Geneva: Reproductive Health and Research, World Health Organization (2000). WHO/RHR/FPP/00.02.
- ⁷Huggins, G.R. and Cullins, V.E. Fertility after contraception or abortion. *Fertility and Sterility* 54(4):559-573 (1990).
- ⁸Simpson, J.L. and Phillips, O.P. Spermicides, hormonal contraception and congenital malformations. *Advanced Contraception* 6(3):141-167 (1990).
- ⁹Harlap, S., Shiono, P.H., and Ramcharan, S. Congenital abnormalities in the offspring of women who used oral and other contraceptives around the time of conception. *International Journal of Fertility* 30(2):39-47 (1985).
- ¹⁰Savolainen, E., Saksela, E., and Saxen, L. Teratogenic hazards of oral contraceptives analyzed in a national malformation register. *American Journal of Obstetrics and Gynecology* 140(5):521-524 (1981).
- ¹¹Raman-Wilms, L. et al. Fetal genital effects of first-trimester sex hormone exposure: a meta-analysis. *Obstetrics and Gynecology* 85(1):141-149 (1995).

- ¹²Bracken, M.B. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. *Obstetrics and Gynecology* 76(3 Pt 2):552-557 (1990).
- ¹³International Consortium for Emergency Contraception. The Emergency Contraception Newsletter 8(1). (Spring/Summer 2003).
- ¹⁴von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *Lancet* 360(9348):1803-1810 (2002).
- ¹⁵Ellertson, C., Evans, M., Ferden, S., et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. *Obstetrics and Gynecology* 101(6):1168-1171 (2003).
- ¹⁶Rodrigues, I., Grou, F., and Joly, J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. *American Journal of Obstetrics and Gynecology* 184(4):531-537 (2002).
- ¹⁷Bacic, M., Wesselius de Casparis, A., and Diczfalusy, E. Failure of large doses of ethinyl estradiol to interfere with early embryonic development in the human species. *American Journal of Obstetrics and Gynecology* 107(4): 531-534 (1970).
- ¹⁸Marions, L. et al. Emergency contraception with mifepristone and levonorgestrel: mechanism of action. *Obstetrics and Gynecology* 100(1):65-71 (2002).
- ¹⁹Durand, M. et al. On the mechanisms of action of short-term levonorgestrel administration in emergency contraception. *Contraception* 64(4):227-234 (2001).
- ²⁰Hapangama, D., Glasier, A.F., and Baird, D.T. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 63(3):123-129 (2001).
- ²¹Ling, W.Y. et al. Mode of action of dl-norgestrel and ethinylestradiol combination in post-coital contraception. *Fertility and Sterility* 32(3):297-302 (1979).
- ²²Swahn, M.L. et al. Effect of post-coital contraceptive methods on the endometrium and the menstrual cycle. *Acta Obstetrica et Gynecologica Scandinavica* 75(8):738-744 (1996).
- ²³Croxatto, H.B. et al. Effects of the Yuzpe regimen, given during the follicular phase, on ovarian function. *Contraception* 65(2):121-128 (2002).
- ²⁴Muller, A.L., Lladós, C.M., and Croxatto, H.B. Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat. *Contraception* 67(5):415-419 (2003).
- ²⁵Croxatto, H.B., Devoto, L., Durand, M., et al. Mechanism of action of hormonal preparations used for emergency contraception: a review of the literature. *Contraception* 63(3): 111-121 (2001).
- ²⁶Croxatto, H.B., Ortiz, M.E., Muller, A.L. Mechanisms of action of emergency contraception. *Steroids*. In press 2003.
- ²⁷Kesseru, E. et al. The hormonal and peripheral effects of dl-norgestrel in postcoital contraception. *Contraception* 10(4):411-424 (1974).
- ²⁸Kesseru, E. et al. In vitro action of progestogens on sperm migration in human cervical mucus. *Fertility and Sterility* 26(1):57-61 (1975).
- ²⁹Trussell, J. and Raymond, E.G. Statistical evidence concerning the mechanism of action of the Yuzpe regimen of emergency contraception. *Obstetrics and Gynecology* 93(5 Pt 2):872-876 (1999).
- ³⁰ Ling, W.Y. et al. Mode of action of dl-norgestrel and ethinylestradiol combination in postcoital contraception. II. Effect of postovulatory administration on ovarian function and endometrium. *Fertility and Sterility* 39(3):292-297 (1983).
- ³¹Young, D.C. et al. Emergency contraception alters progesterone-associated endometrial protein in serum and uterine luminal fluid. *Obstetrics and Gynecology* 84(2):266-271 (1994).
- ³²Yuzpe, A.A. et al. Post coital contraception-a pilot study. *Journal of Reproductive Medicine* 13(2):53-58 (1974).

- ³³ Kubba, A.A. et al. The biochemistry of human endometrium after two regimens of postcoital contraception: a dl-norgestrel/ethinylestradiol combination or danazol. *Fertility and Sterility* 45(4):512-516 (1986).
- ³⁴ Moggia, A. et al. The use of progestogens as postcoital contraceptives. *Journal of Reproductive Medicine* 13(2):58-61 (1974).
- ³⁵ Raymond, E.G. et al. Effect of the Yuzpe regimen of emergency contraception on markers of endometrial receptivity. *Human Reproduction* 15(11):2351-2355 (2000).
- ³⁶ Taskin, O. et al. High doses of oral contraceptives do not alter endometrial $\alpha 1$ and $\alpha \nu \beta 3$ integrins in the late implantation window. *Fertility and Sterility* 61(5):850-855 (1994).
- ³⁷ Ling, W.Y. et al. Mode of action of dl-norgestrel and thinylestradiol combination in postcoital contraception. III. Effect of preovulatory administration following the luteinizing hormone surge on ovarian steroidogenesis. *Fertility and Sterility* 40(5): 631-636 (1983).
- ³⁸ Trussell, J., Ellertson, C., and Dorflinger, L. Effectiveness of the Yuzpe regimen of emergency contraception by cycle day of intercourse: implications of mechanism of action. *Contraception* 67(3):167-171 (2003).
- ³⁹ Jones, R.K., Darroch, J.E., Henshaw, S.K. Contraceptive use among U.S. women having abortions in 2000-2001. *Perspectives on Sexual and Reproductive Health* 34(6):294-303 (2002).
- ⁴⁰ Chaohua, L. et al. Investigation on knowledge of and attitude to emergency contraception among induced-abortion women. *Reproduction and Contraception* (English edition) 9(2):94-102 (1998). (Results summarized in *Use of Emergency Contraceptive Pills Could Halve the Induced Abortion Rate in Shanghai, China*. Social Science Research Policy Briefs, Series 2. No. 1 [August 2001]. UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development, and Research Training in Human Reproductive Health and Research, World Health Organization.)
- ⁴¹ Glasier, A. and Baird, D. The effects of self-administering emergency contraception. *New England Journal of Medicine* 339(1):1-4 (1998).
- ⁴² Lovvorn, A. et al. Provision of emergency contraceptive pills to spermicide users in Ghana. *Contraception* 61(4):287-293 (2000).
- ⁴³ Ellertson, C. et al. Emergency contraception: randomized comparison of advance provision and information only. *Obstetrics and Gynecology* 98(4):570-575 (2001).
- ⁴⁴ Blanchard, K. et al. Evaluation of an emergency contraception advance provision service. *Contraception* 67(5):343-348 (2003).
- ⁴⁵ Skibiak, J.P. et al. *Testing Strategies to Improve Access to Emergency Contraception Pills: Prescription vs. Prophylactic Distribution*. Population Council (1999).
- ⁴⁶ Piaggio, G. et al. Timing of emergency contraception with levonorgestrel of the Yuzpe regimen. *Lancet* 353(9154):721 (1999).
- ⁴⁷ Aiken, A.M., Sackey, N., and Gold, M.A. That was then, this is now...changes in young women's knowledge, attitudes, and perceived barriers to using emergency contraception. *Journal of Pediatric and Adolescent Gynecology* 16(3):177-178 (2003). Abstract of paper presented at the North American Society of Pediatric and Adolescent Gynecology Meeting (June 2002).
- ⁴⁸ Graham, A., Moore, L., Sharp, D., et al. Improving teenagers' knowledge of emergency contraception: cluster randomized controlled trial of a teacher led intervention. *British Medical Journal* 324:1179 (2002).
- ⁴⁹ WHO Task Force on Postovulatory Methods of Fertility Regulation. Efficacy and side effects of immediate post coital levonorgestrel used repeatedly for contraception. *Contraception* 61 (5):303-308 (2000).
- ⁵⁰ Heise, L. et al. *Ending Violence Against Women*. Population Reports, Series L, No. 11. Baltimore: Johns Hopkins University School of Public Health, Population Information Program (December 1999).

Module A Tools List

Special Note: The information contained in some of these documents may not be updated to reflect 2003 published research regarding timing and dosage (see the ICEC statement on timing and dosage for updated, accurate information on these topics).

- ECPs should be used as soon as possible after unprotected intercourse, but can be used within 120 hours.
- Levonorgestrel-only ECPs can be administered in one, 1.5 mg dose.*

Statements on ECPs by International Organizations, Agencies, and Major Donors of Contraceptive Commodities

■ ACOG News Release

This statement in support of emergency contraception issued by ACOG can be found online at http://www.acog.org/from_home/publications/press_releases/nr02-28-01-2.cfm.

■ ICEC Evidence-Based Policy Statements

ICEC has issued a set of five statements with accurate, up-to-date information on improving access, emergency contraception and medical abortion, repeat use, mechanism of action, and timing and dosage. They can also be accessed online at <http://www.cecinfo.org/html/res-downloadable-mtrls.htm>.

■ FIGO Ethics Committee Report

This statement provides the guidelines issued by the FIGO Ethics Committee on use, access, and provision of emergency contraception. The statement was originally printed in *Guidelines in Emergency Contraception, International Journal of Gynecology & Obstetrics* 77:171-175 (2002).

■ IPPF Statement

This document presents information issued by the IPPF International Medical Advisory Panel about provision of emergency contraception in family planning programs worldwide. The statement developed May 2000 and revised in October 2003.

* von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *Lancet* 360(9348):1803-1810 (2002).

■ **USAID and UNFPA Statements**

Two of the major donors of contraceptives for developing-country family planning programs, UNFPA and USAID, have provided statements supporting the provision of ECPs. Statements of both agencies clarifying the types and levels of support they offer are provided.

■ **WHO Statement on Emergency Contraception**

This statement by WHO articulates the safety, efficacy, and ease of emergency contraception use. It was originally printed as WHO Fact Sheet No. 244 (June 2000).

Resources for Developing Messages for Policy Makers

■ **Annotated Bibliography of Core Evidence-Based Research on Emergency Contraception.**

This annotated bibliography contains annotations of the articles referenced in Module A: Information for Policy Makers. Exceptions include those articles summarized in either “Statistical Evidence Concerning the Mechanism of Action of the Yuzpe regimen of emergency contraception” or “Mechanism of Action of Hormonal Preparations Used for emergency contraception: A Review of the Literature,” both of which are included in this bibliography. Additionally, articles pertaining to studies conducted on oral contraceptives and domestic violence are not included in this bibliography. The annotations provide key data and summaries of studies that will be useful in advocacy and education campaigns.

■ **Key Facts About Emergency Contraception**

A fact sheet summarizing key points about emergency contraception . This document can be modified and adapted to emphasize or highlight particular issues, tailoring it to the environment in which advocacy activities take place.

ACOG NEWS RELEASE

Embargoed until February 28, 2001
5:00 PM EST



ACOG Supports Safety and Availability of Over-the-Counter Emergency Contraception

WASHINGTON, DC -- The American College of Obstetricians and Gynecologists (ACOG) has issued new and revised documents on the safety and availability of emergency oral contraception (EC). ACOG says the fallback contraceptive method -- a regimen of oral contraceptives that must be taken within 72 hours after unprotected intercourse -- has the potential to reduce by half the 3 million unintended pregnancies occurring each year in the US.

ACOG supports making EC available to women over the counter in a designated (prepackaged) product, according to its recent **Statement Supporting the Availability of Over-the-Counter Emergency Contraception**. "The time has come for women to have access to a product that they need," reports ACOG, referring to the ongoing barriers to women's access to the drug. Citing the FDA's declaration that EC is safe and effective in preventing pregnancy, ACOG believes "emergency oral contraception can meet the FDA criteria for over-the-counter availability."

In **Emergency Oral Contraception**, a revised Practice Bulletin issued today, ACOG has updated its recommendations to physicians regarding the safety and efficacy of prescription EC. ACOG provides charts on how to combine common prescription oral contraceptives in dosages that provide EC, and has now added information on two EC designated products, Preven and Plan B.

In another effort to increase women's access to EC, ACOG notes that during routine gynecologic visits, physicians may wish to offer patients an advance prescription for EC, for use in any future emergency. EC should be taken within 72 hours of unprotected intercourse, but may provide the greatest efficacy if taken within 24 hours, says ACOG.

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The American College of Obstetricians and Gynecologists is the national medical organization representing nearly 40,000 physicians who provide health care for women.

International Consortium for Emergency Contraception

Policy Statement (July 2003)

Improving Access to Emergency Contraception



Prompt, easy and affordable access to emergency contraception within 120 hours of unprotected sex can reduce the rate of unwanted pregnancies and abortions.¹ Despite endorsement of emergency contraception by major health organizations such as the World Health Organization, and greater availability of dedicated Emergency Contraceptive Pills (ECPs), access remains limited for most women throughout the world.

Why do Women Need Improved Access to Emergency Contraception?

- Studies have shown that the earlier an emergency contraception regimen is taken, the more effective it is at preventing unwanted pregnancies.¹ If access is easy and without a prescription, women can begin to use the regimen without consulting a physician and may begin to use ECPs earlier.²
- In Scotland, women who were provided advance supplies of ECPs were nearly twice as likely to use them as those who sought emergency contraception from a physician. Women with advance supplies of ECPs also experienced lower rates of pregnancy than those who did not have easy access.³ Another study showed that women provided with ECPs in advance were no more likely than those without advance provision to engage in unprotected intercourse.⁴
- In the United States, increased access to emergency contraception was instrumental in averting 51,000 abortions in 2000 and accounted for an estimated 43% decline in abortions between 1994 and 2000.⁵
- The World Health Organization has called emergency contraception safe and effective and has called for greater access to ECPs as well as inclusion of the method in country health programs.

Where is Emergency Contraception Available?

- Several brands of dedicated ECPs are now marketed in the United States, Europe and other countries. Health advocates and private ECPs manufacturers are actively working to achieve broader registration and over-the-counter status for ECPs in both developed and developing countries. At this writing, ECPs are registered in a total of 97 countries worldwide.⁶ Twenty-seven countries in Europe and Africa, and two states in the U.S. offer ECPs directly through pharmacies.⁷

What Are Some of the Barriers to Improving Access to Emergency Contraception?

- In many countries, **lack of government policy** about the method leaves providers unclear about its legal status and insufficiently informed to recommend it to women when needed. Clear policy to promote provision of emergency contraception ensures that it is available in situations such as when contraception has failed as well as among vulnerable groups such as young women and rape survivors.
- Some policy makers and providers are **misinformed** about how ECPs work and believe that they may be an abortifacient. ECPs, like other hormonal contraceptives act in a variety of ways by inhibiting ovulation and preventing sperm and egg from uniting.⁸ While the exact mechanism of action is not fully understood, it is not likely that ECPs prevent implantation of a fertilized egg.⁹ Once implantation of the egg has begun, ECPs are ineffective and will not interfere with an established pregnancy or harm a developing embryo.¹⁰⁻¹¹

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- **Most women are unaware of the existence of emergency contraception**, thus resulting in little demand for the product. Women must be sufficiently aware of the method before it is needed in order to initiate use within the required time frame. Improvements in awareness may come through health care providers, public service communication campaigns as well as through the availability of dedicated ECPs in pharmaceutical outlets.
- **Unclear service delivery protocols** may impede women's access to emergency contraception by requiring unnecessary medical screening to receive the product. While counseling may be desirable when recommending emergency contraception, it is not indispensable to its correct use¹².
- **Prescription requirements** may result in women needlessly delaying use of ECPs beyond the recommended time frame for its use. Past studies have shown that women understand labeling on emergency contraception¹³ and have used it safely and effectively suggesting that involvement of a medical provider is not essential. The established safety record of ECPs and the public health benefits from improved access at the point of sale justify a change in its regulatory status.¹⁴

Recommendation

Improved access to emergency contraception has the potential to avert unwanted pregnancies and abortions worldwide. To achieve this public health benefit, policy makers should include the method in medical and legal protocols, providers should inform women about emergency contraception and women should have the ability to obtain the method without a medical prescription.

References

1. Piaggio G, von Hertzen H, Grimes DA, Van Look PF. "Timing of Emergency Contraception with Levonorgestrel or the Yuzpe Regimen", *Lancet* 1998; 353, 721.
2. Trussell J, Duran V, Schochet T, Moore K, "Access to Emergency Contraception", *Obstetrics & Gynecology*, 2000, 95, 267-70.
3. Glasier A, Baird D. "The Effects of Self-Administering Emergency Contraception", *New England Journal of Medicine*, 1998; 339:1.
4. Ellerton C, Ambardekar S, Hedley A, et al; "Emergency Contraception: Randomized Comparison of Advance Provision and Information Only", *Obstetrics and Gynecology*, October 2001(4): 570-575.
5. Jones R, Darroch J, Henshaw S; "Contraceptive Use Among U.S. Women Having Abortions in 2000-2001", *Perspectives on Sexual and Reproductive Health*, February 2003.
6. International Consortium for Emergency Contraception; Meeting Report, November 2002.
7. American Society for Emergency Contraception; Meeting Report, November 2002.
8. Marions L, Hultenby E, Lindell I, Sun X, Sjöbl B, Danilsson K; "Emergency Contraception with Mifepristone and Levonorgestrel: Mechanism of Action", *American College of Obstetricians and Gynecologists*, 2002; 100; 1: 65-71.
9. IPPF Medical Bulletin, December 2002.
10. Bacic M, Wesseltius de Casparis A, Diczfalusy E. "Failure of large doses of ethinyl estradiol to interfere with early embryonic development in the human species." *Am J Obstet Gynecol* 1970;107(4):531-534.
11. FDA. Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception. Notice; Federal Register, February 1997; 62(37): 8610-8612.
12. Raymond E, Chen P, Dalebout S. "Actual use" study of emergency contraceptive pills provided in a simulated over-the-counter manner. *Obstetrics and Gynecology*, in press.
13. Raymond E, Dalebout S, Camp S; "Comprehension of a Prototype Over-the-Counter Label for an Emergency Contraceptive Pill Product." *Obstetrics and Gynecology* 2002; 100:342-9.
14. Ellerton C, Trussell J, Stewart P, Winkoff B; "Should Emergency Contraceptive Pills Be Available Without Prescription?", *Journal of American Women's Medical Association*; 1998; 56, 5: 226-229.

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International Consortium for Emergency Contraception

Policy Statement (July 2003)



Emergency Contraception and Medical Abortion

Emergency contraceptive pills (ECPs) are a safe and effective means of preventing pregnancy after unprotected sexual intercourse^{1,2}. The use of ECPs cannot terminate or interfere with an established pregnancy and will not harm a developing embryo.^{3,4} ECPs work very differently than medical abortion (abortion pills); however, confusion between emergency contraception and medical abortion agents can present a barrier to broader access to emergency contraception.

What is the difference between emergency contraception and medical abortion?

ECPs are a back up contraceptive method used to prevent a pregnancy after unprotected sex or contraceptive failure. Medical abortion is a non-surgical option for terminating an established pregnancy at an early stage.

ECP regimens consist of the same hormones used in many brands of oral contraceptives (levonorgestrel only or combined estrogen and progestin) in a modified dose that is taken within five days (120 hours) of unprotected intercourse. ECPs are effective only *before* a pregnancy is established, defined as implantation of a fertilized egg in the lining of a woman's uterus. ECPs, like other hormonal contraceptives act in a variety of ways by inhibiting ovulation and preventing sperm and egg from uniting.⁵ While the exact mechanism of action is not fully understood, it is not likely that ECPs prevent implantation of a fertilized egg.⁶ Once implantation of the egg has begun, ECPs are ineffective and will not interfere with an established pregnancy or harm a developing embryo.^{7,8}

Drugs used to provide medical abortion (mifepristone and misoprostol) are distinct from emergency contraceptive pills in that they are used to terminate an existing pregnancy up to 7 weeks after implantation. Existing medical abortion agents work in one of two ways: they either block the hormones required to sustain an existing pregnancy or they stimulate uterine contractions to disrupt the pregnancy.

Why is this distinction important?

Confusion about the two methods can lead to barriers to ECPs access. While medical abortion regimens are administered under a health care provider's supervision, use of ECPs does not require prior medical screening. Women can determine their need for ECPs and self-administer them safely.⁹ There are no contraindications to use of ECPs, dosage of the most common levonorgestrel-only ECP products is uniform, and ECPs have no known important interactions with other medications and will not cause birth defects if pregnancy is not prevented. Increasingly ECPs are sold over the counter through pharmacies. Twenty-seven countries in Europe and Africa offer ECPs directly via pharmacists, and a petition is pending before the U.S. Food and Drug Administration to make EC available over-the-counter without a prescription in the U.S.

How is broader access to ECPs important to women's reproductive rights and health?

ECPs are the only available means of preventing a pregnancy after unprotected intercourse that a woman can self-administer. As such, ECPs have important potential impact for preventing unintended pregnancies and abortion worldwide. In the United States, increased access to emergency contraception has been estimated to have prevented 51,000 abortions in 2000 and accounted for an estimated 43% decline in abortions between 1994 and 2000.¹⁰

For more information, visit www.cecinfo.org

Recommendation

ECPs are a safe and effective back up means of preventing unintended pregnancy. No medical or legal barriers should exist to limit their use. Policy makers, medical professionals and other health advocates should continue to highlight the safety of ECPs and to promote their universal availability, timely access and affordability to women and couples worldwide, with the understanding that ECPs are not a replacement for, but rather are an adjunct to regular contraceptive practice.

References

1. Food and Drug Administration. Prescription drug products; certain combined oral contraceptives for use as postcoital emergency contraception. Federal Register 1997; 62:8610-8612.
2. Emergency Contraception: A Guide for Service Delivery. Geneva: World Health Organization; 1998. WHO/FRH/FPP/98.19
3. *ibid*
4. Bacic M, Wesselius de Casparis A, Diczfalussy E. Failure of large doses of ethinyl estradiol to interfere with early embryonic development in the human species. *Amer J Obstet Gynecol* 1970;107(4):531-534.
5. Marions L, Hulthén K, Lindell I, Sun X, Ståhl B, Danilsson K; *Emergency Contraception with Mifepristone and Levonorgestrel: Mechanism of Action*; American College of Obstetricians and Gynecologists, 2002; 100, 1: 65-71.
6. IPPF Medical Bulletin; December 2002
7. Bacic M, Wesselius de Casparis A, Diczfalussy E. Failure of large doses of ethinyl estradiol to interfere with early embryonic development in the human species. *Amer J Obstet Gynecol* 1970;107(4):531-534.
8. FDA. *Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception*; Notice, Federal Register, February 1997, 62(37); 8610-8612.
9. Glasier A., D Baird, The effects of self-administering emergency contraception. *New England Journal of Medicine*. 1998; 339:1-4.
10. Jones R, Darroch J, Henshaw S; *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, Perspectives on Sexual and Reproductive Health; February 2003.

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International Consortium for Emergency Contraception

Policy Statement (July 2003)



How Do Emergency Contraceptive Pills Work to Prevent Pregnancy?

Mechanism of Action

Like all hormonal contraceptives, emergency contraceptive pills may work in a variety of ways. The precise mechanism of action of ECPs in a particular case cannot be determined and depends on the time in a woman's menstrual cycle when intercourse occurred and when ECPs were taken.¹

Emergency contraceptive pills:

- Inhibit or delay an egg from being released from the ovary when taken before ovulation
 - May prevent sperm and egg from uniting
 - May stop a fertilized egg from attaching to the uterus
- Several studies have provided direct evidence that both combined estrogen and progestin regimens and progestin-only ECPs act by preventing or delaying ovulation, perhaps by inhibiting follicular development and maturation or the release of the ovum itself.^{2,6} Some researchers have proposed that this may be the principal or only mechanism of action.
- Statistical evidence suggests that ECPs could not be as effective as data indicate if they only worked by interfering with ovulation.⁷
- No direct clinical data exist regarding mechanisms other than the inhibition, alteration, or delay of ovulation.⁸
- Researchers have found that ECP regimens containing levonorgestrel may interfere with sperm transport or penetration. ECPs may prevent sperm from reaching the egg by thickening the cervical mucus resulting in the trapping of sperm. Alterations in the tubal transport of sperm, egg, or zygote may also occur.^{3,9}
- Some studies have shown changes in histologic and biochemical features of the endometrium after treatment with combined ECPs, suggesting that they may act by impairing endometrial receptivity to implantation of a fertilized egg.^{6,10,12} However, other studies have shown no such effects with both the combined and levonorgestrel-only regimens,^{2,5,13,14} and it is not clear that the observed changes would be sufficient to prevent implantation.
- Another potential mechanism of action that may occur at the level of the ovary is interference with corpus luteum sufficiency and responsiveness.⁵ The corpus luteum is responsible for producing estrogen and progesterone, which prepare the endometrium for implantation.
- Even if emergency contraceptive pills altered endometrial receptivity, other steps preceding implantation may be altered enough to prevent a pregnancy at an earlier stage.¹⁵
- ECPs are ineffective once implantation has begun. Data from studies of high-dose oral contraceptives indicate that ECP regimens cannot interfere with an established pregnancy.^{16,17}

For more information, visit www.cecinfo.org

Why is the Mechanism of Action of ECPs Significant?

- The mechanism of action of emergency contraceptive pills is important for some users, healthcare providers, policy makers and manufacturers because of sensitive ethical and legal debates.⁶
- Exploring the mechanism of action of emergency contraceptive pills is central to understanding the difference between emergency contraception and early medical abortion. The two have occasionally been confused. ECPs are effective only in the first few days following intercourse before pregnancy begins, while medical abortion is an option for women in the early stage of pregnancy. At least five days elapse between unprotected intercourse and the establishment of a pregnancy, defined as implantation of a fertilized egg in the lining of a woman's uterus. ECPs work prior to implantation to prevent pregnancy by delaying or preventing ovulation, or possibly by blocking fertilization or altering endometrial receptivity; they cannot interrupt an established pregnancy or harm a developing embryo.⁶

Recommendation

For women to make an informed choice about using emergency contraceptive pills, they must know that ECPs may prevent pregnancy through various mechanisms of action that will not interfere with an established pregnancy.

References

1. Grimes DA, Raymond EG. Emergency contraception. *Ann Intern Med* 2002; 137(3): 180-189.
2. Menions L, Halperin E, Landell I, Sun X, Stahl B, Gonzalez Danielsson K. Emergency contraception with mifepristone and levonorgestrel: mechanism of action. *Obstet Gynecol* 2002; 100(1): 65-71.
3. Durand M, del Carmen Cravito M, Raymond EG, Duran-Sanchez O, De la Cruz-Hinojosa M, Castell-Rodriguez A, Schawon R, Larrea F. On the mechanisms of action of short-term levonorgestrel administration in emergency contraception. *Contraception* 2001; 64(4): 227-34.
4. Hapogama D, Glaser AF, Bard DT. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 2001; 63(3): 123-9.
5. Swahn ML, Westlund P, Johansson B, Bygdeman M. Effect of post-coital contraceptive methods on the endometrium and the menstrual cycle. *Acta Obstet Gynecol Scand* 1996; 75(8): 738-44.
6. Ling WY, Robichaux A, Zayd L, Wixson W, MacLeod SC. Mode of action of DL-norgestrel and ethinylestradiol combination in postcoital contraception. *Fertil Steril* 1979; 32(3): 297-302.
7. Trussell J, Raymond EG. Statistical evidence concerning the mechanism of action of the Yuzpe regimen of emergency contraception. *Obstet Gynecol* 1999; 93(5 pt 2): 872-76.
8. Trussell J, Ellerton C, Dorfinger L. Effectiveness of the Yuzpe regimen of emergency contraception by cycle day of intercourse: implications for mechanism of action. *Contraception* 2003; 67(3): 167-171.
9. Kessers E, Gamboa F, Wemphal N, Farada J. The hormonal and peripheral effects of d-norgestrel in postcoital contraception. *Contraception* 1974; 10(4): 411-24.
10. Kessers E, Camacho-Omega P, Landahn G, Schoplin G. In vitro action of progestogens on sperm migration in human cervical mucus. *Fertil Steril* 1975; 26(1): 57-61.
11. Young DC, Wiehle RD, Joshi SG, Penderster AN 3rd. Emergency contraception alters progesterone-associated endometrial protein in serum and uterine luminal fluid. *Obstet Gynecol* 1994; 84(2): 266-71.
12. Yuzpe AA, Thurlow EJ, Ranney L, Leyden JL. Post-coital contraception. -A pilot study. *J Reprod Med* 1974; 13(2): 53-8.
13. Raymond EG, Lovely LF, Chen-Mok M, Seppala M, Kumar RJ, Lessey BA. Effect of the Yuzpe regimen of emergency contraception on markers of endometrial receptivity. *Hum Reprod* 2000; 15(11): 2351-5.
14. Tashir O, Brown EW, Young DC, Penderster AN, Wiehle RD. High doses of oral contraceptives do not alter endometrial alpha 1 and alpha v beta 3 integrins in the late implantation window. *Fertil Steril* 1994; 61(3): 850-5.
15. Cronetto HB, Devoto L, Durand M, Escamez E, Larrea F, Nagle C, Ortiz ME, Ventana D, Vega M, von Hertzen H. Mechanism of action of hormonal preparations used for emergency contraception: a review of the literature. *Contraception* 2001; 63(3): 111-21.
16. FDA. Prescription drug products: certain combined oral contraceptives for use as postcoital emergency contraception. Notice. Federal Register February 25, 1997; 62(37): 9610-9612.
17. Baine M, Wesselaar de Casparis A, Diczfalusy E. Failure of large doses of ethinyl estradiol to interfere with early embryonic development in the human species. *Amer J Obstet Gynecol* 1970; 107(4): 531-534.

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International Consortium for Emergency Contraception

Policy Statement (July 2003)

Repeated Use of Emergency Contraception: The Facts



Repeat use of emergency contraception or over reliance on the method is a concern sometimes mentioned by health providers, policy makers and the public.¹⁻⁵ The facts are that emergency contraception is safe, even when used more than once in a cycle. In addition, studies have found that repeat use of more than a few times in a one year period is uncommon, even when women have easy access to the method.

How often do women use ECPs more than a few times a year?

Studies investigating how often women use ECPs have found that using it more than four times in one year is uncommon. A study of general practice patients in the UK found that less than one percent of ECP users requested ECPs more than three times in a year.⁶ Another study among family planning clinic attendees in the UK found that 23% had used the method more than twice in a year, but only 6% had used it more than four times.

Does increasing the availability of ECPs lead women to adopt more risky sexual behavior, to abandon ongoing contraceptive methods, or to repeatedly use ECPs?

Studies around the world indicate that advance provision of ECPs does not lead women to abandon ongoing contraception, to have unprotected sex more frequently, or to repeatedly use ECPs.⁹⁻¹⁰ In fact, the studies show that women with easier access to ECPs are more likely to use it when needed, potentially reducing unintended pregnancy.

Are ECPs safe when used repeatedly?

The World Health Organization guidelines on ECP service delivery state, "Although frequent use of emergency contraceptive pills is not recommended, repeat use poses no health risks and [health risks] should never be cited as a reason for denying women access to treatment."¹¹

There are no medical contraindications to ECPs when used occasionally, for example, once a month or less. If use exceeds this amount, the contraindications to regular combined or progestin-only oral contraceptives *might* apply.¹² There is no direct data on this issue, however, and extrapolating from long-term oral contraceptive use might not be appropriate because ECP use involves much shorter exposure to hormones. A woman would have to use combined ECPs approximately 3 times in a month in order to be exposed to the same amount of estrogen as a long-term low-dose combined pill user. Such a frequency of use is rare. Even for women with contraindications to estrogen, taking ECPs is likely safer than carrying an unwanted pregnancy to term. In such cases, women should be offered progestin-only ECPs as often as needed.

ECPs cause more side effects than other hormonal methods, although these are not serious and last only a short time. The most common side effects are menstrual irregularities and nausea.¹³ In a study of repeat postcoital use of 0.75 mg of levonorgestrel (half the dosage used in the levonorgestrel-only ECP regimen), 70% of the participants reported menstrual irregularities. A high proportion of the women in this study dropped out early because of the side effects. This may indicate that the side effects themselves would deter repeat use of ECPs.¹⁴

For more information, visit www.cecinfo.org

How effective are ECPs when used repeatedly?

Biologically, there is no reason to suspect that the effectiveness of ECPs would decrease with repeat use; however this issue has not been studied. It is important to note that the cumulative failure rate of ECPs over a number of uses is higher than the failure rate for one use because of the simple statistical fact that the probabilities of the individual events are compounded.

Recommendation

Medical and behavioral research conducted to date does not provide any basis for limiting the number of times that women use ECPs, in a year or in a month. In every single case, ECPs are safer than pregnancy, in particular when pregnancies are unintended and women do not have access to safe abortion services. Women should use ECPs as often as needed. However, counseling should include the following messages: ECPs are less effective at preventing pregnancy than other non-emergency hormonal contraceptive methods; women choosing to take ECPs should start the method as early as possible after unprotected sex, since ECPs are more effective the earlier they are initiated;¹⁵ ECPs don't protect against STIs and that barrier methods should be used if the woman is at risk. Finally, repeat ECP use may indicate that a woman requires further counseling on other contraceptive options.¹²⁻¹³

References

1. Gold M, Schein A, Coupey SM. Emergency contraception: a national survey of adolescent health experts. *Fam Plann Perspect* 1997;29:15-9.
2. Ziebland S, Graham A, McPherson A. Concerns and cautions about prescribing and deregulating emergency contraception: a qualitative study of GPs using telephone interviews. *Family Pract* 1998;15(5):449-56.
3. Sorhaindo A, Becker D, Fletcher H, Garcia SG. Emergency contraception among university students in Kingston, Jamaica: a survey of knowledge, attitudes, and practices. *Contraception* 2002 Oct;66(4):261-8.
4. Blanchard K, Bungay H, Furedi A, Sanders L. Evaluation of an EC advance provision service. *Contraception*, forthcoming.
5. Rothschild TJ. Switching emergency contraception to over-the-counter status. [Correspondence]. *NEJM* 2003;348:82-3.
6. Rowlands S, Lawrenson R. Repeated use of hormonal emergency contraception by younger women in the UK. *Br J Fam Plann* 2000;26:138-43.
7. Roizen J, Garside R and Barnett L. Repeat use of emergency contraception: how frequent is it? *J Family Plan Reprod Health Care* 2001;27(4):197-202.
8. Steiner M, Piedrahita C, Joanis C, Glover J, Spruyt A. Condom breakage and slippage rates among study participants in eight countries. *Int Fam Plan Perspect* 1994;20(2):55-8.
9. Glasier A and Baird D. The effects of self-administering emergency contraception. *NEJM* 1998;339(1):1-4.
10. Turner AN and Ellertson C. How safe is emergency contraception? *Drug Saf* 2002;25(10):695-706.
11. World Health Organization (WHO). *Emergency Contraception A guide for service delivery*. Geneva: WHO; 1998.
12. World Health Organization (WHO). *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. 2nd ed. Geneva: WHO; 2000.
13. Grimes DA and Raymond EG. Emergency contraception. *Ann Intern Med* 2002; 137(3):180-9.
14. Task Force on Post-Ovulatory Methods of Fertility Regulation. Efficacy and side effects of immediate postcoital levonorgestrel used repeatedly for contraception. *Contraception* 2000;61:303-8.
15. Task Force of Post-Ovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998; 352:428-33.

International Consortium for Emergency Contraception

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International Consortium for Emergency Contraception

Policy Statement (July 2003)

Regimen Update



Dosage and Timing

Recent studies have provided new information concerning the regimen for levonorgestrel-only emergency contraceptive pills (ECPs). Study results indicate that a single dose of 1.5 mg of levonorgestrel can substitute for two 0.75 mg doses 12 hours apart. New research also indicates that ECPs can prevent pregnancy up to five days (120 hours) after unprotected intercourse (both levonorgestrel and Yuzpe regimens).

- **A single dose of 1.5 mg (levonorgestrel-only ECP)**

A World Health Organization (WHO) multi-center randomized trial in ten developed and developing countries found a single 1.5 mg dose of levonorgestrel to be as effective in reducing the risk of pregnancy as two 0.75 mg doses taken 12 hours apart. Side effects did not differ between the two regimens. [1] A Nigerian study corroborated this finding that a single 1.5 mg dose of levonorgestrel is both effective and safe. [2] This single dose approach simplifies the use of levonorgestrel for emergency contraception.

- **ECPs should be taken as soon as possible, but can be used up to 5 days (120 hours) after unprotected intercourse**

Levonorgestrel-only emergency contraception is effective in preventing a high proportion of pregnancies up to five days (120 hours) after unprotected intercourse according to the findings of a WHO multicenter randomized trial. [1] The combined estrogen and progestin (Yuzpe) regimen also reduces the risk of pregnancy for up to five days according to data from a Canadian study. [3] However, results from the WHO study showed a significant trend towards a lower efficacy the longer the delay between treatment and unprotected intercourse, and earlier WHO trials have indicated that pregnancy risk increases over time with delay of treatment. [1, 4] These results underscore the importance of providing ECPs to women who seek treatment beyond 72 hours. To maximize the effectiveness of the method, however, women should be encouraged to take ECPs as soon as possible after unprotected intercourse. ECPs are not effective after implantation.

For more information, visit www.cecinfo.org

Recommendation

While product labeling and information provided by ECP manufacturers is not likely to change in the immediate future, providers are encouraged to update their ECP protocols to reflect this new information. Based on evidence to date, providers should advise women to take a single 1.5 mg dose of the levonorgestrel-only ECP regimen. Providers should continue to promote ECP treatment as soon as possible following unprotected intercourse, but provide ECPs up to 120 hours after unprotected sex, as needed.

References

1. von Hertzen H, Piaggio G, Ding J, et al. "Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial." *Lancet* 2002; 360 (9348): 1803-1810
2. Arowojolu AO, Okewole IA, Adekunle AO. "Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians." *Contraception* 2002; 66:269-273
3. Rodrigues I, Grou F, Joly J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. *Am J Obstet Gynecol* 2001; 184(4):531-537
4. 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): 428-433

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Guidelines Issued by the FIGO Ethics Committee

Background

1. The Committee recognizes that basic human rights to health include the freedom to control sexual and reproductive health. Individuals also have the right to enjoy the benefits of new scientific knowledge in sexual and reproductive health.
2. The Committee noted its prior statement¹ that “Failure to advocate policies that will improve women’s health care and advance women’s rights broadly will deleteriously influence the health care of individual patients cared for by the Ob/Gyn.”
3. In unprotected intercourse, emergency contraception is highly effective in diminishing the number of unwanted pregnancies without the need of an abortion.^{2,3} Early evidence suggests that abortion rates among teenagers drop following access to information and use of emergency contraception.

Recommendations

1. Early access to hormonal emergency contraception improves the success rate and therefore decreases health risks. Therefore, at a public policy level, the medical profession should advocate that emergency contraception be easily available and accessible at all times to all women.
2. Emergency contraception is not medically appropriate as an ongoing contraceptive method. Physicians have the obligation to assure accurate information is available regarding emergency contraception, as well as discuss future strategies for individuals to avoid the need for emergency contraception.
3. Access to emergency contraception should be an essential component of immediate care for women who suffer rape and are exposed to pregnancy. Adolescents because of their special vulnerability in society form another group for whom emergency contraception should be made easily available.

¹ The Role of the Ob/Gyn as Advocates for Women’s Health page 6 Recommendations on Ethical Issues in Obstetrics and Gynecology by The FIGO Committee for the Ethical Aspects of Human Reproduction and Women’s Health, August 2000.

² Definition of pregnancy: “Natural human reproduction is a process which involves the production of male and female gametes and their union at fertilization. Pregnancy is that part of the process that commences with the implantation of the conceptus in a woman, and ends with either the birth of an infant or an abortion.” (The FIGO Committee for the Ethical Aspects of Human Reproduction and Women’s Health, August 2000). Published in the International Journal of Gynecology and Obstetrics, March 1999 volume 64/3:317.

³ “Induced abortion may be defined as the termination of pregnancy using drugs or surgical intervention after implantation and before the conceptus has become independently viable” (WHO definition of a birth: 22 weeks menstrual age or more.) (The FIGO Committee for the Ethical Aspects of Human Reproduction and Women’s Health, August 2000). Published in the International Journal of Gynecology and Obstetrics, March 1999 volume 64/3:318.

This material originally printed in the *International Journal of Gynecology and Obstetrics* 77:171-175 (2002). Reprinted with permission from the International Federation of Gynecology and Obstetrics (FIGO) Ethics Committee. Note: Committee documents do not represent FIGO’s official position; rather they represent the views of a group of independent experts.

International Planned Parenthood Federation Statement on Emergency Contraception

Introduction

Despite the availability of highly effective methods of contraception, many pregnancies are unplanned and unwanted. Such pregnancies can result in abortion and carry an excess risk of morbidity and mortality. The risk of pregnancy with one unprotected act of sexual intercourse can be as high as one in three, depending on the cycle day of exposure in relation to ovulation. For the woman exposed to unprotected sexual intercourse, e.g., lack of contraceptive use, condom breakage, missed pills, or sexual assault, emergency contraception can be used to prevent an unwanted pregnancy.

Since the mid-1960s, the post-coital use of certain orally administered steroid hormones has been shown to be effective in preventing pregnancy. In addition, intrauterine devices (IUD) and the anti-progestogen mifepristone are also highly effective for emergency contraception.

Hormonal Methods

Two commonly available oral regimens have proved to be safe and effective for emergency contraception.

Levonorgestrel-only regimen

The most convenient regimen is a single dose consisting of 1.5 mg levonorgestrel taken as soon as possible after unprotected intercourse; alternatively, one dose of 0.75 mg levonorgestrel can be taken as soon as possible after unprotected intercourse followed by the same dose taken 12 hours later.

Levonorgestrel pills are more effective the sooner they are taken after unprotected intercourse. They are most effective if taken within 3 days (72 hours). However, there is still some effect up to 5 days after unprotected intercourse.

Where pills containing 0.75 mg levonorgestrel are not available, 0.03 mg levonorgestrel pills which are used for regular contraception offer a possible alternative. Twenty-five of these mini pills should be taken initially, and a further twenty-five 12 hours later. There is anecdotal evidence to support this regimen, but no clinical studies have evaluated its efficacy.

Combined estrogen-progestin regimen

This regimen consists of two 50 µg ethinyl estradiol/0.25 mg levonorgestrel pills, or four 30 µg ethinyl estradiol/0.15 mg levonorgestrel pills, taken as soon as possible within 72 hours after unprotected intercourse, followed by a second similar dose 12 hours later. This method shows little efficacy after 72 hours from unprotected intercourse.

Choice of method

The levonogestrel-only regimen should be the first choice where available because it is more effective and is less likely to cause nausea than the combined regimen. However, the combined regimen should remain an option where the levonorgestrel-only regime is less accessible and more costly, as in many countries.

Mechanism of action

Hormonal emergency contraception achieves its contraceptive effect by several mechanisms depending on the time in a woman's cycle it is taken. It can inhibit or delay ovulation and may also interfere with ovum and sperm transport and fertilization. Studies differ on whether hormonal emergency contraception can cause changes in the endometrium that would be sufficient to interfere with implantation. There is no evidence that hormonal emergency contraception dislodges the embryo after implantation has occurred. Hormonal emergency contraception does not cause an abortion".

Efficacy

Various studies have shown that the levonorgestrel-only regimen reduces the risk of pregnancy by 60%-93% or more after a single act of intercourse, and the combined regimen reduces it by 56%-89%. In direct comparisons, the levonorgestrel regimen has been shown to be substantially more effective than the combined regimen. ECPs are not as effective as consistent and correct use of most modern contraceptive methods.

Eligibility criteria

No known contraindications exist to the use of hormonal emergency contraception. Although this method is not indicated for a woman with a known or suspected pregnancy, it will not affect the course of her pregnancy, or harm the foetus. There is no need for a physical examination or pregnancy test before it is provided.

Side-effects

Nausea and vomiting are common among women using the combined regimen and considerably less common among women using the levonorgestrel-only regimen. When the combined regimen is used, anti-emetic pre treatment may be considered; with the levonorgestrel-only regimen this is unnecessary.

If vomiting occurs within one hour after taking a dose, it is common practice to repeat the dose. However, there is no evidence that this improves efficacy; indeed, vomiting can be an indication that the hormone has been absorbed. In case of vomiting, further pills may be administered vaginally. Although there are no clinical data supporting the efficacy of this practice, contraceptive steroid hormones are known to be readily absorbed from the vagina.

Other side-effects with hormonal EC include abdominal pain, fatigue, headache, dizziness, and breast tenderness. After the use of hormonal emergency contraception, menses usually occur at the regular time, but may be either earlier or later. Some women may experience irregular bleeding or spotting after taking ECPs.

Drug interactions

Women should be advised that the effectiveness of ECP may be reduced if they are taking drugs which reduce the efficacy of regular oral contraceptives (including but not limited to rifampicin, griseofulvin, barbiturates). At the current time there is insufficient information on drug interactions to make any specific recommendations on increased ECP dosing schedules.

Frequency of use

Hormonal emergency contraception should not be used for routine pregnancy prevention since the cumulative pregnancy rate for frequent use of ECP is higher than that with regular contraception. However, if unprotected intercourse occurs in a cycle where the emergency contraception has already been used it can be repeated. Women should understand that emergency contraception pills may not protect them from the possibility of pregnancy from episodes of unprotected intercourse more than 5 days before the ECPs are taken or from intercourse after the pills are taken.

In cycles where unprotected intercourse has occurred more than once, hormonal emergency contraception can be used. However, efficacy will be influenced by the time interval since the first act of unprotected intercourse. If the woman is already pregnant because of earlier intercourse, emergency contraception will not be effective.

Mifepristone

A single dose of mifepristone 10 mg taken within 5 days of unprotected intercourse is highly effective for emergency contraception. It has a low incidence of side-effects. However, 9 -18% of women experience a delay of menses of more than 5 days. Women should be counselled appropriately. A major constraint from the use of mifepristone is its limited availability.

Copper-releasing IUDs

The copper-releasing IUD is also highly effective for emergency contraception. It can reduce the chance of pregnancy by more than 99% when inserted within 5 days of unprotected intercourse. This method may be particularly useful when the client is considering its use for long-term contraception and/or when the hormonal regimens are less effective because more than 72 hours have elapsed. When using an IUD for emergency contraception, the eligibility criteria are the same as those for regular use of these devices.

Essential information for users

Information on emergency contraception should be available to all women who may need the method. Whether contained in product pamphlets or offered by a service provider, it should include guidance on the following:

- Correct use
- Possible side-effects and their management

- Risk of pregnancy (detection and management of possible failure of the ECPs to prevent pregnancy)
- Changes in the menstrual pattern
- Preferences for regular contraception
- STI risk

Risk of pregnancy

If menstruation is delayed by more than one week from the expected time or if it is much lighter than normal, emergency contraception may have failed and the woman should consider the possibility that she may be pregnant. In the event of a pregnancy, she should be counselled on the available options and her decision should be respected and supported. If she chooses to continue with the pregnancy, she should be reassured that there is no evidence that hormonal emergency contraception affects the foetus. The use of hormonal emergency contraception has no impact on future fertility.

Regular contraception

After use of emergency contraception, women should employ another method of contraception (e.g. condoms) if she continues to have sexual intercourse. If oral contraception is chosen, it can be started the day after the ECP regimen is completed). Women who began regular use of hormonal contraception immediately after emergency contraception should be advised to expect withdrawal bleeding three weeks after starting the pills. Women choosing a long-acting hormonal contraceptive should start the method after the onset of the first menstrual period or after pregnancy has been excluded. Women opting for the IUD for emergency contraception should be advised that the IUD will provide ongoing protection from pregnancy from the time of insertion: follow-up should be arranged after the expected date of menstruation to ensure that pregnancy has been prevented and for counselling on regular contraception. Women who choose to continue using the IUD for long-term contraception should subsequently receive the same services as any other IUD user. If a woman chooses to have the IUD removed, she should be advised to come back during menstruation for removal and initiation of another contraceptive method.

Sexually transmitted infections (STIs)

Emergency contraception does not protect against sexually transmitted infections. Women who have had unprotected intercourse should be advised about the possibility of STIs. Those who may have been exposed to STIs should be offered testing or presumptive treatment that cures the commonly occurring STIs and be counselled appropriately. For women who may have been exposed to HIV, post exposure prophylaxis with ARVs should be offered where available and with appropriate counselling and follow-up.

Advocacy and Access

IPPF member associations have an important role to play in increasing awareness of emergency contraception and advocating for its easy access in local communities. Member associations should undertake activities in the following areas:

Increasing the availability of emergency contraception:

Member associations providing services should include emergency contraception in their method mix and integrate emergency contraception into their national programmes. Associations can play a lead role in ensuring the existence of a dedicated EC product in their countries and campaigning for its over-the-counter status.

Advocacy and dissemination

Member associations should disseminate information on emergency contraception and how to obtain it, by means, including mass media, training of service providers, and sexual and reproductive health education programmes. Information geared specifically to the needs of young people is particularly important.

Increasing access to supplies and services

Emergency contraception should be widely available in clinical and non clinical settings, such as community-based services, social marketing programmes, and the commercial sector. Member associations can work to increase access through the advance provision of emergency contraception to individual women.

Overcoming obstacles

Member associations should initiate locally relevant efforts aimed at removing the multiple social, cultural and religious barriers to emergency contraception.

Statement developed by the International Medical Advisory Panel (IMAP), May 2000 and revised in October 2003 IMAP reserves the right to amend this Statement in the light of further developments in this field.

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United Nations Population Fund (UNFPA)

Statement on Emergency Contraception

The United Nations Population Fund (UNFPA) endorses the view that the aim of family planning programs must be to enable couples and individuals to decide freely and responsibly the number and spacing of their children and to have the information and means to do so and to ensure informed choices and make available a full range of safe and effective methods (ICPD para 7.12). In response to government requests, UNFPA can provide supplies for those methods including progestin-only dedicated emergency contraceptive pills. UNFPA is committed to reducing the incidence of abortion and it does not promote or support abortion in any country. UNFPA supports emergency contraception as a means for expanding contraceptive choice and reducing abortion. In line with accepted definitions of medical science, the World Health Organization states, “Emergency contraceptive pills do not interrupt pregnancy and thus are no form of abortion.” By making emergency contraception more widely available, reproductive health care providers of family planning can help reduce unplanned pregnancies, many of which result in unsafe abortion and take a large toll on women’s health. Emergency contraception also is an essential part of treatment for women who are victims of sexual assault. UNFPA shares the view that EC should be promptly available as a back-up for unprotected intercourse. With its major role in the prevention of both unintended pregnancies and recourse to abortion, EC is a valuable addition to reproductive health programs. UNFPA collaborates with national authorities to improve access to EC as part of high-quality care for reproductive health.

United States Agency for International Development (USAID)

Statement on Emergency Contraception

USAID is committed to providing a full range of contraceptive options. Providing information about ECPs has become a medical norm. In fact, the American College of Obstetricians and Gynecologists (ACOG) now recommends that women be informed of ECPs as standard good medical practice. The USFDA action further reinforces this norm.¹ Accordingly, USAID supplies information about the use of ECPs in a variety of its technical and training materials, and supports sharing information with family planning clients about this contraceptive option. Another role for USAID-supported programs is to collect data on the need, use, and potential impact of ECPs in participating countries; to conduct operations research on how the provision of ECPs can be integrated within family planning and other reproductive health programs and which groups would benefit most from having ECPs available; and biomedical research on the mechanism of action, use, and effectiveness of ECPs. Although USAID-supplied oral contraceptive pills are among the FDA-approved formulations that can be used for emergency contraception, USAID does not currently fund separate packaging of pills for this purpose nor has USAID purchased any of the two USFDA-approved dedicated ECP products. USAID is able to help interested Missions seek out other sources of donor support for the provision of a dedicated EC product.

¹ The USFDA published a formal notice on February 25, 1997, in the *Federal Register* stating that any one of six different [and now many more] common brands of combined oral contraceptive pills, all containing norgestrel or levonorgestrel and ethinyl estradiol, are safe and effective for use as emergency contraception up to 3 days after unprotected sex.

World Health Organization Emergency Contraception Statement

Emergency Contraception

Emergency contraception refers to contraceptive methods that can be used by women in the first few days following unprotected intercourse to prevent an unwanted pregnancy. Emergency contraceptive methods are effective and safe for the majority of women who may need them, as well as being simple to use.

Who may need emergency contraception?

Any woman of reproductive age may need emergency contraception at some point to avoid an unwanted pregnancy. It is meant to be used in situations such as:

- after voluntary sexual intercourse that took place with no contraceptive protection;
- after incorrect or inconsistent use of regular contraceptive methods or when there has been an accidental failure of other contraceptive methods such as:
- condom breakage or slippage;
- miscalculation of the infertile period when using periodic abstinence or failure to abstain from sexual intercourse during the fertile days;
- expulsion of an intrauterine device (IUD);
- failed coitus interruptus, when ejaculation has occurred in the vagina or on the external genitalia;
- failure to take oral contraceptives for more than 3 days;
- being late for a contraceptive injection;
- when a woman has been a victim of sexual assault and has had no contraceptive protection.

Methods of emergency contraception

The most common methods of emergency contraception are:

- high doses of combined oral contraceptives (COCs) containing ethinyl estradiol and levonorgestrel (Yuzpe regimen).
- high doses of progestogen-only pill containing levonorgestrel.

Mode of action

Emergency contraception pills (ECPs) are thought to prevent ovulation, fertilization, and/or implantation. ECPs are not effective once the process of implantation has begun, and will not cause abortion.

Efficacy

After a single act of unprotected sexual intercourse, the Yuzpe regimen fails in about 2 percent of women who use it correctly (the chances of pregnancy are approximately four times greater when no emergency contraceptive is used). The progestogen-only regimen is equally effective.

Eligibility criteria

The World Health Organization (WHO) has drawn up medical eligibility criteria for the use of emergency contraception pills based on the relative health risks and benefits of the method for women with given conditions.

The sole contraindication for the use of emergency contraception pills is pregnancy. Emergency contraception pills should not be given to a woman who has a confirmed pregnancy primarily because they will not be effective. Experts believe there is no harm to a pregnant woman or fetus if emergency contraceptive pills are inadvertently used during early pregnancy. Emergency contraceptive pills are for emergency use only and not recommended for routine use because of the higher possibility of failure compared to regular contraceptives and the increase in side effects such as nausea and vomiting. However, their repeated use poses no known health risks.

Further reading

Consortium for Emergency Contraception. Emergency Contraceptive Pills. A resource packet for health care providers and Programme Managers. 1996.

Wells E, Crook B, Muller N. Emergency Contraception: A resource Manual for Providers. PATH, 1997

World Health Organization. Emergency Contraception: A guide for service delivery. WHO/FRH/FPP/98.19

World Health Organization. Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use. WHO/FRH/FPP/96.9.

Annotated Bibliography of Core Evidence-Based Research on Emergency Contraception

Special Note:

This annotated bibliography contains annotations of most of the articles referenced in Module A: Information for Policy Makers. Exceptions include those articles summarized in either *Statistical Evidence Concerning the Mechanism of Action of the Yuzpe Regimen of Emergency Contraception* (Trussell and Raymond) or *Mechanism of Action of Hormonal Preparations Used for Emergency Contraception: A Review of the Literature* (Crozzatto, Ortiz, and Muller), both of which are included in this bibliography. Additionally, articles pertaining to studies conducted on oral contraceptives and domestic violence are not included in this bibliography.

Aiken, A.M., Sackey, N., and Gold, M.A. That was then, this is now...changes in young women's knowledge, attitudes, and perceived barriers to using emergency contraception. *Journal of Pediatric and Adolescent Gynecology* 16(3):177-178 (2003).

This abstract describes a study presented at the North American Society of Pediatric and Adolescent Gynecology's annual conference on May 16, 2003, in Philadelphia, Pennsylvania. The purpose of the study was to compare the knowledge, attitudes, and perceived barriers to ECP use between two samples of young women, one from 1996 and the other from 2002. One hundred young women were recruited in 2002 from the same adolescent clinic as the 1996 sample. Seventy-seven percent were African American and 80 percent of the participants had been sexually active. Participants watched a 4 ½ minute video and received a review of emergency contraception. They were then interviewed using a semistructured questionnaire, nearly identical to the one used in 1996, about sexual and contraceptive history as well as knowledge of and experience with ECPs. Results showed that a greater percentage of the 2002 participants (74 percent) had knowledge of ECPs than participants in the 1996 study (51 percent). Thirteen percent of the 2002 group had used ECPs compared to only 3 percent in the 1996 group. Of those who had heard of ECPs, 96 percent of those in 2002 knew where to get it compared to 81 percent of the 1996 group, and 53 percent in 2002 vs. 21 percent in 1996 knew the correct time limits for use. The authors concluded that young women attending this urban clinic had an increased level of knowledge and awareness of and positive attitudes toward ECPs. Interventions focused on improving knowledge on the correct use, timing, side effects, costs, and barriers to ECPs among adolescents can further increase their use of this method.

Blanchard, K. et al. Evaluation of an emergency contraception advance provision service. *Contraception* 67(5):343-348 (2003).

This paper presents the results of a questionnaire and telephone survey to evaluate an ECP advance provision service in the United Kingdom. Women requesting ECPs were asked to fill out a questionnaire, and those who provided telephone contact information were called for more detailed information. Over a three-month period, 485 women who requested ECPs

were given questionnaires. Two hundred and fifty-nine women returned the questionnaire (53 percent response rate). Of those women who returned the questionnaire, 54 were followed up for further interviews and 31 were interviewed. Women were supportive of advance provision and indicated that it would not change their regular contraceptive use. They supported wider dissemination of information and services, especially for younger women. Several women thought that potential “abuse” or health risks of ECPs warranted strict control, while others were supportive of ECPs. The authors concluded that women and providers need accurate information about ECPs, advance provision is important especially in countries where ECPs are not yet available from pharmacists, and uptake of advance provision might be improved by subsidizing the cost of the method.

Bracken, M.B. Oral Contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. *Obstetrics and Gynecology* 76(3 Pt 2):552-557 (1990).

This meta-analysis was conducted on prospective epidemiologic studies on oral contraceptive pills (OCPs) and congenital malformations to determine the overall relative risk of an association between congenital malformations and regular oral contraceptives. The analysis found very strong evidence against the hypothesis that exposure to OCPs in pregnancy is related to a risk of malformations in stillborn babies or live newborns. Given that much of the safety data on ECPs is extrapolated from studies conducted on regular OCPs, this study has been cited in several papers on ECP safety, highlighting the implausibility that inadvertent use during pregnancy might have an effect on a developing fetus.

Chaohua, L. et al. Investigation on knowledge of and attitude to emergency contraception among induced-abortion women. *Reproduction and Contraception* (English edition) 9(2):94-102 (1998).

This paper describes a study conducted in Shanghai, China, to assess women’s knowledge, attitudes, and acceptance of emergency contraception in order to inform strategies to improve service provision. The study enrolled 606 women presenting for medical abortion at MCH clinics in Shanghai. A face-to-face, questionnaire-based interview was administered. Results indicated that 29 percent of the women presenting for abortion were aware of emergency contraception, and of those 97 percent (168) were aware of the emergency contraceptive pill. Seven of who knew about emergency contraception knew of the IUD. Of those who knew about emergency contraception, 25 percent did not think it was available in China. Only 25 women who knew about the ECP knew the correct timing, while 5 of the 7 who knew about the IUD knew its correct timing. The proportion of women willing to use emergency contraception was 86 percent in general and 91 percent among those who had known about emergency contraception prior to the study. Of those willing to use emergency contraception, 83 percent preferred the pill. The low knowledge of emergency contraception availability among those women who knew about emergency contraception shows the need for education and awareness around this method in China.

Croxatto, H.B. et al. Effects of the Yuzpe regimen, given during the follicular phase, on ovarian function. *Contraception* 65(2):121-128 (2002).

This paper discusses the results of a study undertaken to assess the extent to which the Yuzpe regimen, or half of the normal dose of that regimen, prevents ovulation when given during the follicular phase. Sixty women were enrolled in the study. All women received both a placebo and drug during the study, but in randomized order. The women were divided into six groups which differed by dosage and size of the leading follicle at treatment time (12

to 14, 15 to 17, or 18 to 20 mm). Results showed that ovulation did not occur during the ensuing five days in 65 percent of the participants nor in 40 percent of the participants who received the full and half dose, respectively, at follicle size 12-17 mm. In 18 percent of those participants who received a placebo, no ovulation occurred during the critical period. At follicle size 18 to 20 mm, ovulation was not prevented by treatment. In most of the treated cycles, sex steroid and plasma gonadotropin levels were significantly depressed during the critical period, even when follicular rupture occurred. The authors concluded that the Yuzpe regimen is effective in suppressing or postponing ovulation to the point exceeding the fertile life of spermatozoa. The lack of ovulation that occurs as well as the disruption of the ovulatory process with this method during the critical period is the likely cause of its contraceptive effect. Data did not warrant recommendation of the use of half a dose of the Yuzpe regimen.

Croxatto, H.B., Devoto, L., Durand, M., et al. Mechanism of action of hormonal preparations used for emergency contraception: a review of the literature. *Contraception* 63(3):111-121 (2001).

A comprehensive review of the literature on the mechanism of action for hormonal contraception is presented to describe how ECPs act to prevent pregnancy and to identify gaps in the literature. One hundred and two studies are included in this analysis. Information contained in this article includes a discussion of the current modes of use, efficacy, and side effects of the Yuzpe regimen, levonorgestrel, and mifepristone; the effects of postcoital administration of steroids upon fertility in nonprimate animals; studies in nonhuman primates; and clinical studies focusing on the effects of the Yuzpe regimen administered before and after the luteinizing hormone surge, progesterone-regulated endometrial proteins, and an appraisal of the possible mechanisms of action for the levonorgestrel-only method and mifepristone. The results of this analysis are further summarized in “Emergency contraception pills: how do they work?” *IPPF Medical Bulletin* 36(6) (December 2002).

Croxatto, H.B., Oritz, M.E., Muller, A.L. Mechanisms of action of emergency contraception. *Steroids*. 68(10-13):1095-8 (2003).

This article highlights two key animal studies and discusses results of several other studies undertaken to determine exactly how emergency contraceptive pills work to prevent pregnancy. In one study looking at the rat, the effects of acute treatment with levonorgestrel upon ovulation, fertilization, and implantation were evaluated. Results showed that LNG partially or totally inhibited ovulation depending on both the dosage and time of treatment. It did not, however, have an effect on fertilization or implantation when given shortly before or after mating or before implantation. Researchers concluded that no postfertilization effects were present in the rat. Results of this study, “Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat,” were published in *Contraception* in 2003. A similar study on Cebus monkeys (currently in press) was conducted to test the effect of acute LNG treatment on ovulation in nonmated cycles and on the pregnancy rate in mated cycles. LNG given twice in the follicular phase inhibited ovulation but had no effect on the pregnancy rate when given after mating. Researchers concluded that acute postcoital LNG treatment had no postfertilization effects in the Cebus monkeys.

Durand, M. et al. On the mechanisms of action of short-term levonorgestrel administration in emergency contraception. *Contraception* 64(4):227-234 (2001).

A study to understand better the effects of short-term administration of levonorgestrel on

the pituitary-ovarian axis, corpus luteum function, and endometrium at different stages of the ovarian cycle was undertaken in 45 healthy, surgically sterilized women with regular menstrual cycles over two cycles. During the second menstrual cycle (treatment cycle), two doses of 0.75 mg levonorgestrel were given 12 hours apart. Women received the treatment in four groups during different phases of their menstrual cycles: Group A during the follicular phase (day 10), Group B during the periovulatory phase (luteinizing hormone [LH] surge), Group C during the postovulatory phase (48 hours after urinary LH detection), and Group D during the late follicular phase (just prior to LH surge). During both the control and treated cycles, urinary LH assays performed by each woman at home were used as the benchmarks for transvaginal ultrasounds and serum LH assays to begin. The ultrasounds and serum assays were used to determine ovulation. During the complete luteal phase, serum estradiol and progesterone were measured. Each woman also underwent an endometrial biopsy nine days after LH detection during both the control and treated cycles in order to find indications of hormone action after LH surge. Results of the study suggest that interference of levonorgestrel on the LH preovulatory surge is strongly dependent on the stage of follicular development. Anovulation observed in Group A is a result of disrupting the development and/or hormone activity of the follicle only in the preovulatory stage. Levonorgestrel did not affect the corpus luteum function or endometrium when given during the peri- and postovulatory stages.

Ellertson, C. et al. Emergency contraception: randomized comparison of advance provision and information only. *Obstetrics and Gynecology* 98(4):570-575 (2001).

This article reports the results of a study undertaken in India to determine whether several courses of ECPs provided in advance to women would tempt women using barrier methods to take more risks with their effective ongoing contraceptives. Most of the women enrolled in the study were condom users. Four hundred and eleven women who used barrier contraceptives were randomly assigned to one of two groups: those to receive information and three courses of ECPs in case of need and those to receive only information (which included where they could go to obtain ECPs if needed). Results indicated that women in both groups reported nearly identical rates of unprotected intercourse. Among women who reported unprotected intercourse, those with advance provision were almost twice as likely to use ECPs as those who received information only. No woman used ECPs more than once. Ninety-eight percent of women with advance supplies said having ECPs did not make them take more chances with condoms.

Ellertson, C., Evans, M., Ferden, S., et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. *Obstetrics and Gynecology* 101(6):1168-1171 (2003).

Current protocols call for initiation of emergency contraception within 72 hours of unprotected intercourse. This study questioned whether initiation of ECPs after 72 hours could have any benefits. Investigators conducted a prospective observational study to determine the effectiveness of the Yuzpe regimen when started between 72 and 120 hours after unprotected intercourse. They examined effectiveness rates for 111 women who used the regimen between 72 and 120 hours and 675 women who used the same regimen but within 72 hours. Results indicate that the failure rates differed by 2 to 4 percent between the groups, with the standard regimen having a greater effectiveness as compared to the regimen that was initiated after 72 hours. The authors note that their study lacked power due to the small sample size, but refer to the 72-hour cutoff as “unnecessarily restrictive.” They argue

that the regimen can substantially reduce the risk of pregnancy even after 4 to 5 days of unprotected intercourse.

Glasier, A. Emergency postcoital contraception. *New England Journal of Medicine* 337(15):1058-1064 (1997).

In this review article, Glasier defines ECPs' mechanism of action, the indications for ECPs, and the various forms of ECPs. Glasier also describes the controversy and misconception that ECPs are an abortifacient. The author explains that "the balance of evidence suggests that the most widely used hormonal emergency contraceptive [at the time], estrogen plus progestin, works mainly by inhibiting or delaying ovulation." Glasier emphasizes that ECPs interfere with ovulation and not fertilization and it states that implantation is not achieved until at least seven days after ovulation; ECPs taken within 72 hours [or up to five days] therefore cannot be considered an interruption of pregnancy. Glasier also notes that availability and access to ECPs are critical to achieving maximum effectiveness. Because the ECP regimen must start within 72 hours of unprotected intercourse, a woman has to know about the methods before the need for it arises. Recommendations are made for increased knowledge about how ECPs work, particularly its timing after unprotected intercourse, and improved accessibility.

Glasier, A. Safety of emergency contraception. *Journal of American Medical Women's Association* 53(5 Suppl 2):219-221 (1998).

This paper describes the safety records of combined oral contraceptives (ethinyl estradiol and levonorgestrel), levonorgestrel only, mifepristone, and the IUD when used as emergency contraception. The author determines that based on available information, all four methods have considerable data confirming their safety. The case is made that emergency contraception is often over-medicalized, (i.e., requiring a gynecologic exam or prescription from physician) and that consideration should be given to making ECPs available without a prescription wherever possible.

Glasier, A. and Baird, D. The effects of self-administering emergency contraception. *New England Journal of Medicine* 339(1):1-4 (1998).

The authors compared the use of ECPs in 553 women who were provided with a replaceable supply of hormonal ECPs to be taken at home (the treatment group), and 530 women who could obtain ECPs through a doctor (the control group). The study found that women in the treatment group were no more likely to use emergency contraception repeatedly than women in the control group, and that nearly all women used emergency contraception correctly. The authors concluded that making emergency contraception more easily attainable may reduce the rate of unwanted pregnancies and does not pose any risks or increase the likelihood of repeat use.

Graham, A., Moore, L., Sharp, D., et al. Improving teenagers' knowledge of emergency contraception: cluster randomized controlled trial of a teacher-led intervention. *British Medical Journal* 324:1179 (2002).

This paper presents the results of a cluster randomized controlled trial undertaken to assess the effectiveness of a teacher-led intervention to improve teenagers' knowledge about emergency contraception. Participants in the trial included 1,974 boys and 1,820 girls aged 14 to 15 years of age from 24 mixed-sex secondary schools in England. Teachers were instructed on how to teach students about emergency contraception and then gave students

a single lesson on emergency contraception. Questionnaires were given to students as a baseline and at six months. Information gathered via the questionnaire included knowledge of the correct use of ECPs as well as time limits for ECPs and IUDs as emergency contraception. It also included sexual activity, use of emergency contraception, and intention to use emergency contraception in the future. Results showed that those in the intervention group showed higher levels of knowledge of emergency contraception than those in the control group and there were no differences between the two groups in terms of those who had never had sex, had used emergency contraception, or intended to use it in the future. The authors concluded that the intervention did not change participants' sexual activity or increase use of emergency contraception, but that it did significantly improve the proportion of students who knew the correct timing of emergency contraception for both the IUD and ECPs.

Hapangama, D., Glasier, A.F., and Baird, D.T. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 63(3):123-129 (2001).

This article discusses the results of a study conducted to test the hypothesis that levonorgestrel (LNG) acts as an ECP by disrupting the preovulatory luteinizing hormone (LH) surge which causes a delay in ovulation. Twelve women using nonhormonal contraceptive methods or practicing abstinence enrolled in the study. Each woman was observed for four menstrual cycles, one acting as a prestudy cycle to familiarize the women with the methods of detecting LH surge and days of high fertility with a monitor. The women were divided into two groups; both groups received either LNG or a placebo during the first and third cycles (six women took LNG in the first cycle and six took it in the third cycle), and all women received a placebo during the second. Results showed that all 12 women took LNG before the LH peak and most likely ovulation. Researchers concluded that there is reason to believe that LNG taken immediately before ovulation can delay ovulation and therefore act as an emergency contraceptive. However, there may be other explanations for the mechanism of action of LNG such as altering the endometrium, interfering with sperm motility, and altering cervical mucous.

Jones, R.K., Darroch, J.E., and Henshaw, S.K. Contraceptive use among U.S. women having abortions in 2000-2001. *Perspectives on Sexual and Reproductive Health* 34(6):294-303 (2002).

Based on a review of contraceptive use patterns among 10,683 women in the United States who received abortion services during 2000 and 2001, this study suggests that more than 50,000 abortions were averted by use of ECPs in 2000. Of the women in this review, 1.3 percent reported having taken ECPs to prevent the pregnancy. Estimates by other researchers suggest that for each pregnancy that occurs after use of ECPs, three pregnancies are prevented. The authors conclude that the increased use of ECPs in the United States may account for a significant part of the recent reduction in abortions nationally. Interestingly, 46 percent of women did not use a contraceptive method in the month they became pregnant, mainly because of perceived low risk of pregnancy and concerns about contraception. The authors suggest that women and men need more opportunities to discuss issues such as when and whether to have sexual intercourse in a relationship, methods of pregnancy prevention, and appropriate timing of childbearing.

Lovvorn, A. et al. Provision of emergency contraceptive pills to spermicide users in Ghana. *Contraception* 61(4):287-293 (2000).

This study evaluated the effect of advance provision and on-demand provision services on ECP use and unprotected intercourse among women using spermicide for contraception. Two hundred and eleven women at four family planning clinics in Accra, Kumasi, Takoradi, and Nkawkaw were enrolled in the study; all were counseled on the importance of correct spermicide use, and each was given at least forty spermicide tablets. At two of the clinics (advance clinics), women were given one packet of ECPs to take home and use if unprotected intercourse occurred and they were instructed to return to the clinic if the pills were used, lost, or given away. At the other two clinics (on demand clinics), women were counseled about ECPs and advised to return to the clinic within three days of unprotected intercourse if they should need ECPs. In all of the clinics, women used ECPs after 78 percent of unprotected sexual acts, but ECPs were used more promptly by women who had the pills at home. The data did not suggest that the availability of ECPs affected the frequency of unprotected intercourse.

Marions, L. et al. Emergency contraception with mifepristone and levonorgestrel: mechanism of action. *Obstetrics and Gynecology* 100(1):65-71 (2002).

This study examined the effects of levonorgestrel and mifepristone on ovarian function, endometrial development, and markers of endometrial receptivity to determine their mechanisms of action. Six women were treated with a single dose of mifepristone (10 mg) and six women were treated with two doses of levonorgestrel (0.75 mg) 12 hours apart. Treatment with both mifepristone and levonorgestrel before ovulation inhibited the luteinizing hormone surge, showing no significant differences between the means of luteinizing hormone measurements. The results conclude that both regimens are effective methods of emergency contraception. The authors note that ECPs may be used on any day of the menstrual cycle but it is only when sexual intercourse takes place during a 6-day period that ends on the estimated day of ovulation that there is a risk of pregnancy. Additionally, the data indicates that the 10 mg mifepristone treatment delayed the development of the follicle or inhibited ovulation and the levonorgestrel treatment inhibited the luteinizing hormone peak. It is emphasized that mifepristone may be used up to 120 hours after intercourse, but administration of levonorgestrel should be started very soon after intercourse. The authors conclude that the primary mechanism of action for both mifepristone and levonorgestrel is inhibition of ovulation rather than inhibition of implantation. However, the effect on the endometrium and the fallopian tubes may also contribute to the mifepristone's effectiveness.

Muller, A.L., Lladós, C.M., and Croxatto, H.B. Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat. *Contraception* 67(5):415-419 (2003).

This paper presents the results of a study conducted to determine the effect of acute treatment with levonorgestrel (LNG) on ovulation, fertilization, and implantation in the rat. The main interventions were administration of LNG relative to ovulation, mating, and fertilization. Results showed that LNG, depending on time of treatment and/or dosage, either totally or partially inhibited ovulation. LNG had no effect on fertilization or implantation when given either shortly before or after mating, or before implantation. The authors conclude that LNG, when administered in doses much higher than those used in women, had no postfertilization effects in the rat.

Norris Turner, A. and Ellertson, C. How safe is emergency contraception? *Drug Safety* 25(10):695-706 (2002).

This article reviews the safety information available about emergency contraception using direct and indirect biomedical and social science literature, the extensively documented safety profile of regular oral contraceptives, and over 30 years clinical experience with hormonal emergency contraception. The effectiveness, dosage, and timing of the Yuzpe regimen, progestin-only pills, copper-bearing IUDs, and mifepristone are included in this discussion. Research indicating that hormonal contraceptives may be effective up to 120 hours after intercourse is included. Concerns about several safety issues (including venous disease, arterial disease, future fertility, potential birth defects, adverse side effects, and drug interactions associated with emergency contraception) are allayed using research from long-term use of regular oral contraceptives. Public health concerns that increased access to emergency contraception will result in abandonment of ongoing contraception and repeat use and encourage promiscuity and unsafe sexual practices are also challenged using data from published studies. The authors conclude that emergency contraception is safe both from the individual and public health perspectives and that increased availability and use should be encouraged.

Piaggio, G. et al. Timing of emergency contraception with levonorgestrel of the Yuzpe regimen. *Lancet* 353(9154):721 (1999).

In this letter, authors of the study *Randomized Controlled Trial of Levonorgestrel versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception* responded to a letter suggesting that randomization itself could not account for the discrepancy between this study and an earlier study showing no decline in efficacy with delay in treatment time. The authors reviewed the results of their study and adjusted the estimate of the odds ratio successively for age, weight, body mass index, gravidity, cycle length, day of the cycle in which unprotected intercourse took place, and previous use of ECPs. The results of this adjustment gave almost the same results as the original analysis. The authors concluded, based on the statistically significant effect seen with both regimens, the consistency of results from their trial and that of a previous trial, and biological plausibility, that the effect of delayed treatment on efficacy is real. Moreover, delaying the first dose of ECPs by 12 hours increased the odds of pregnancy by nearly 50 percent.

Raymond, E.G. et al. Effect of the Yuzpe regimen of emergency contraception on markers of endometrial receptivity. *Human Reproduction* 15(11):2351-2355 (2000).

The purpose of this study was to determine if the Yuzpe regimen altered endometrial integrity expression or other markers of uterine receptivity in order to determine the contraceptive action of the Yuzpe regimen. Conflicting studies have indicated that the regimen may inhibit implantation of the fertilized ovum due to a disrupted endometrium. Nineteen women were followed after taking 100 mg of ethinyl oestradiol and 1 mg of norgestrel on the day of a luteinizing hormone surge and repeating this dose 12 hours later. Investigators found that treatment at this timing in a woman's cycle did not prevent ovulation, alter endometrial structure, or affect endometrial proteins. The authors postulated that the regimen may affect endometrial function in ways undetectable by the tests performed in the study.

Rodrigues, I., Grou, F., and Joly, J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. *American Journal of Obstetrics and Gynecology*. 184(4):531-537 (2002).

This article discusses the results of the first study undertaken to determine the effectiveness of the Yuzpe regimen as an emergency contraceptive when taken between 72 and 120 hours after unprotected intercourse. Three hundred and seventeen women were included in the final analysis, with 131 receiving treatment within 72 hours and 169 receiving treatment between 72 and 120 hours after unprotected intercourse. Results showed that the pregnancy rate was 0.8 percent for the group that received treatment within 72 hours and 1.8 percent for those who received it between 72 and 120 hours. Effectiveness rates (reduction in pregnancy rate attributable to treatment) decreased from 87 to 90 percent for those receiving it within 72 hours to 72 to 87 percent for those who received it between 72 and 120 hours. There was a statistically significant reduction in pregnancy for both groups. Results indicate that although women should be counseled to receive ECPs as soon after unprotected intercourse as possible, ECPs can still prevent pregnancy after 72 hours and up to 120 hours.

Skibiak, J.P. et al. *Testing Strategies to Improve Access to Emergency Contraception Pills: Prescription vs. Prophylactic Distribution*. Population Council (1999).

This publication describes the results of a study conducted in Zambia to compare two approaches to ECP provision. Three groups of women were selected to receive either: a pack of ECPs for future use (intervention), an advanced prescription for ECPs that could be redeemed at a participating health center (intervention), or information and counseling about ECPs only (control). The strategies were compared in terms of their effectiveness at communicating information about ECPs, reducing wastage, facilitating timely access to ECPs, and limiting the use of ECPs to emergencies only. Results indicated that neither approach had significant differences in communicating information, but advanced provision dramatically reduced the time between unprotected intercourse and administration of treatment. There also was an indication that advanced provision led women to be more likely to use ECPs, which was attributed to two major factors. First, given that women in the study had a very poor contraceptive use rate overall, advance supplies may have affected women's desire to use routine hormonal contraceptive methods. Second, having advance supplies of ECPs may have altered women's ability to negotiate condom use with her partner. The authors concluded that advance provision is safe and effective and should be further explored, but that greater provider awareness, information, and training about the correct use and potential negative effects of advance provision are needed.

Trussell, J., Ellertson, C., and Dorflinger, L. Effectiveness of the Yuzpe regimen of emergency contraception by cycle day of intercourse: implications for mechanism of action. *Contraception* 67(3):167-171 (2003).

This paper presents the results of a literature review aimed at providing evidence about the mechanism of action of the Yuzpe regimen. It includes studies that reported women treated by the Yuzpe regimen and their resulting pregnancies by cycle day of intercourse relative to expected day of ovulation. The authors found that effectiveness was significantly higher when intercourse occurred on or before the second day before ovulation. The investigators concluded that inhibiting implantation of a fertilized egg cannot be the primary mechanism of action. If it were, one would not expect effectiveness to be so much lower when ECPs are taken after intercourse that occurs later in the cycle.

Trussell, J. and Raymond, E.G. Statistical evidence concerning the mechanism of action of the Yuzpe regimen of emergency contraception. *Obstetrics and Gynecology* 93(5 Pt 2):872-876 (1999).

An analysis of published studies on the statistical evidence on the effectiveness of the Yuzpe regimen was conducted to learn more about its mechanism of action. Studies included in the analysis were those with information on effectiveness, number of women treated on each cycle day and the outcome of the treatment, probability of conception by menstrual cycle day, and occurrence of ovulation in women treated with the Yuzpe regimen. Forty estimates of the actual effectiveness of the Yuzpe regimen were compared with the maximum theoretical effectiveness if the regimen worked only by preventing or delaying ovulation. The researchers concluded that the Yuzpe regimen could not be as effective as other studies indicate if it worked only by preventing or delaying ovulation. Further investigation needs to be carried out in order to determine more fully the mechanisms of action of this regimen.

von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *Lancet* 360(9348):1803-1810 (2002).

This randomized, double-blind clinical trial among 4,136 women in 15 clinics in 10 countries compared the efficacy and side effects of three regimens for emergency contraception taken within five days of unprotected intercourse: a single 10 mg dose of mifepristone, two 0.75 mg doses of levonorgestrel taken 12 hours apart, and a single dose of 1.5 mg levonorgestrel. All three regimens are very effective at preventing pregnancy if taken within five days (120 hours) of unprotected intercourse, though the study showed a significant trend towards a lower efficacy the longer the delay between treatment and unprotected intercourse. Side effects were mild and did not differ significantly between the groups. The finding that a single dose of 1.5 mg levonorgestrel is as effective in reducing the risk of pregnancy as two 0.75 mg doses taken 12 hours apart has important implications for a simplified emergency contraception regimen.

World Health Organization. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. 2nd ed. Geneva: Reproductive Health and Research, World Health Organization (2000). WHO/RHR/FPP/00.02.

This ground-breaking document summarizes the main recommendations of two scientific working group meetings held at WHO in March 1994 and May 1995 on the medical eligibility criteria for use of various contraceptives. It was updated in 2000. It includes numerous tables clarifying how various health conditions and behaviors should be considered when providing contraceptives. This document is designed for use by policy makers, family planning program managers, and the scientific community in the preparation of guidelines for service delivery of contraceptives.

World Health Organization 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* 352(9126):428-433 (1998).

WHO conducted a double-blind, randomized trial of 1,998 women who requested emergency contraception after one unprotected coitus. Approximately half received levonorgestrel-only ECPs (0.75 mg, repeated 12 hours later), and half received the Yuzpe regimen (100 µg

ethinyl estradiol plus 0.5 mg levonorgestrel, repeated 12 hours later). The crude pregnancy rate was 1.1 percent with the levonorgestrel-only regimen and 3.2 percent with the Yuzpe regimen. The incidence of side effects was significantly lower with the levonorgestrel-only regimen, particularly nausea (23.1 percent vs. 50.5 percent) and vomiting (5.6 percent vs. 18.8 percent). The study also found that the effectiveness of emergency contraception decreased as the interval between administration and intercourse increased.

World Health Organization Task Force on Postovulatory Methods of Fertility Regulation. Efficacy and side effects of immediate post coital levonorgestrel used repeatedly for contraception. *Contraception* 61(5):303-308 (2000).

In order to evaluate the acceptability, safety, and side effects of repeat use of postcoital levonorgestrel, researchers enrolled 295 women with infrequent coitus (defined as 1 to 4 occurrences per month) at six sites. The women were instructed to take a single 0.75mg dose of levonorgestrel orally postcoitally for six months as their only form of contraception. Participants kept a diary of intercourse acts, tablet ingestion, and side effects. The overall probability of pregnancy per treated intercourse act was 1.4 per 1,000, and the calculated Pearl index failure rate was 6.8 pregnancies per 100 woman-years of use (95 percent CI 3.1-12.9). Nearly one-third of women discontinued the study before the six-month period, mainly because of bleeding problems associated with the treatment. Seventy percent of the women had menstrual problems. Other complaints included nausea, breast tenderness, weakness, dizziness, headache, abdominal bloating, loss of libido, depression, and vomiting. Researchers concluded that high-dose, postcoital administration of levonorgestrel pills is suitable for emergency contraception and back-up to the failure of other methods but is unsuitable for use as regular contraceptive methods.

Key Facts About Emergency Contraception

What is emergency contraception?

The term emergency contraception refers to methods used by women within a few hours or a few days after unprotected intercourse to prevent pregnancy before it happens. The most common method of emergency contraception involves taking emergency contraceptive pills (ECPs), which are an elevated dose of hormonal contraceptive pills, as soon as possible after unprotected intercourse and within no more than five days (120 hours). Another emergency contraceptive method is insertion of the intrauterine device (IUD) into a woman's uterus within seven days of unprotected intercourse to prevent pregnancy.

What types of ECPs are used for emergency contraception and how effective are they?

ECPs containing only a progestin (levonorgestrel) or containing both estrogen (ethinyl estradiol) and progestin (levonorgestrel or norgestrel) can be used as contraception after intercourse to reduce the risk of unintended pregnancy. Research demonstrates that the levonorgestrel-only regimen has fewer side effects and is more effective than the combined regimen. Either regimen of ECPs can be taken up to 120 hours after unprotected intercourse, but the sooner after unprotected intercourse that a woman takes ECPs, the lower her risk of pregnancy. If used during the most fertile period, there is a 75 percent and 89 percent reduction in pregnancy risk respectively for women using the Yuzpe and levonorgestrel-only regimens within 72 hours.

Why do women need emergency contraception?

The Global Health Council estimates that nearly 60 million unintended pregnancies occur worldwide each year. Emergency contraception has the potential to prevent millions of these pregnancies. Emergency contraception can be used anytime a woman has unprotected intercourse but does not want to become pregnant. ECPs, which are safe and can be made easily accessible, provide an important opportunity for women who do not wish to become pregnant to prevent pregnancy if contraception fails, sex is forced, or contraception is not used.

Who can use emergency contraception?

All women, even those women who for medical reasons cannot use birth control pills as a regular method of contraception, can use ECPs.

How does emergency contraception work?

ECPs work by interrupting a woman's reproductive cycle. ECPs are effective only before a pregnancy is established (clinically defined as implantation of a fertilized egg in the uterus).^{*} They cannot work after a fertilized egg has been implanted. ECPs primary mechanism of action is the inhibition or delay of ovulation (or the release of an egg from a woman's ovaries).

^{*} The definition provided above is provided within a medical/clinical context. Individuals may have their own beliefs about when a pregnancy begins.

Does emergency contraception cause an abortion?

Medical science considers that a pregnancy has begun once implantation of a fertilized egg in the lining of a woman's uterus is complete. The process of implantation begins six days after fertilization and is completed about one week later. ECPs used during this period prevent pregnancy from occurring before implantation, which is contraception and not abortion. Based on medical definitions, emergency contraception is prevention of pregnancy because it works before implantation. Emergency contraceptives are ineffective once implantation has begun. They cannot cause an abortion if the woman is already pregnant.

Are ECPs safe?

The World Health Organization has stated that there are no absolute contraindications to the use of emergency contraceptive pills due to the small overall hormone dose and short duration of use. ECPs do not have the same contraindications as daily oral contraceptives. Researchers have concluded that no evidence exists to suggest that ECPs will harm a developing fetus.

Is repeat use of ECPs harmful?

Repeat use of ECPs poses no health risks. Experience with ECPs suggests that repeat use within the same cycle is uncommon. Use of levonorgestrel-only ECPs as frequently as four times a month did not reveal negative health risks. While repeat use is not a reason to deny a woman access to ECPs, it is an indication that a woman needs further counseling on routine contraceptive methods, as all other methods are more effective. Women who have regular intercourse (more than four times per month) are not advised to use ECPs as a regular contraceptive method because it is not as effective as regular contraception.

Do ECPs prevent sexually transmitted infections?

ECPs do not protect against HIV/AIDS or other sexually transmitted infections like syphilis, gonorrhea, chlamydia, and herpes.