



# **Emergency Contraceptive Pills: Medical and Service Delivery Guidelines**

Second Edition • 2004

*International Consortium for Emergency Contraception*

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2004

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## CONTENTS

<i>Foreword</i>	4
<i>Summary Service Protocol for Emergency Contraceptive Pills</i>	5
<b>1 Introduction</b>	7
1.1 Definition	7
1.2 Indications	7
<b>2 Emergency Contraceptive Pills</b>	7
2.1 ECP Regimens	7
2.2 Mode of Action	8
2.3 Efficacy	8
2.4 Side Effects, Prevention, and Management	9
2.5 Precautions	9
2.6 Screening	10
2.7 Special Issues	10
2.8 Information for the Client	11
2.9 Counseling	11
2.10 Follow-up	12
2.11 If the Client Becomes Pregnant	12
2.12 Starting or Resuming Regular Contraception after ECP Use	12
<b>3 ECP Service Delivery Systems</b>	13
3.1 Youth	14
3.2 Women Who Have Been Sexually Assaulted	14
<b>Table 1 ECP Formulations</b>	15
<i>Appendix: Use of IUDs for Emergency Contraception</i>	16
<i>References</i>	17
<i>About the International Consortium for Emergency Contraception</i>	19

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## FOREWORD

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Offering emergency contraception is an important way for family planning and other reproductive health programs to improve the quality of their services and better meet the needs of their clients. Emergency contraception is needed because no contraceptive method is 100 percent effective, and few people use their method perfectly every time they have intercourse. Furthermore, emergency contraception is useful in cases of sexual assault.

Emergency contraceptive pills (ECPs), the most commonly used and most convenient form of emergency contraception, are not difficult to provide. Specially packaged ECPs or supplies of regular oral contraceptives that can be used for ECPs are readily available in most places. Providers can be trained easily in the correct use, counseling, and follow-up related to ECPs. Nevertheless, providing ECPs does entail unique service delivery issues, such as the need to ensure rapid access to the method to maximize efficacy and the importance of conveying information about additional, ongoing methods to prevent both pregnancy and sexually transmitted infections after the ECPs are used.

An essential component of programs providing emergency contraception is education, informing women about

this important option before they need it. Because the time frame for treatment is short — efficacy declines with each day or even hour of delay — women need to be aware that emergency contraception is an option, know where they can seek services, and understand that treatment should be started as soon as possible after unprotected or inadequately protected intercourse. Providing emergency contraceptive information and, if practical, supplies of ECPs at the time of a regular family planning or medical visit is one way of ensuring that women have the resources they need to protect themselves from pregnancy in the event of unprotected intercourse or a contraceptive failure.

The organizations that make up the International Consortium for Emergency Contraception have compiled these service delivery guidelines to give family planning and other reproductive health programs and practitioners the information they need to provide ECPs safely and effectively. The recommendations in these guidelines reflect the latest available research on emergency contraception and have been reviewed by internationally recognized reproductive health experts. Local programs should adapt these guidelines as necessary to comply with national or other requirements.

## SUMMARY SERVICE PROTOCOL FOR EMERGENCY CONTRACEPTIVE PILLS

Emergency contraceptive pills (ECPs) are an important option for women who recently have had unprotected intercourse or a contraceptive failure and who do not want to become pregnant. ECPs have been shown to be safe and effective in studies conducted over the past three decades.

### Indication

To prevent pregnancy after unprotected or inadequately protected intercourse.

### Regimens

The two regimens discussed in these guidelines are:

- **Levonorgestrel-only regimen:** 1.50 mg levonorgestrel in a single dose or in two doses of 0.75 mg taken up to 12 hours apart.
- **Combined estrogen-progestin regimen:** two doses of 100 mcg ethinyl estradiol plus 0.50 mg of levonorgestrel taken 12 hours apart.

Treatment with either regimen should be initiated as soon as possible after intercourse because data suggest that efficacy declines substantially with time. Both regimens have been shown to be effective through five days (120 hours) after intercourse. Longer delays have not been investigated.

In some locations, both regimens are available as products formulated and labeled specifically for use as ECPs. Alternatively, ECPs can be formulated from a variety of regular oral contraceptive pills (see Table 1 or [www.cccinfo.org](http://www.cccinfo.org)).

The levonorgestrel-only regimen is preferred because it is more effective and is associated with a lower incidence of side effects.

### Mode of Action

The exact mode of action of ECPs in any given case cannot be known. ECPs have been shown to inhibit or delay an egg from being released from the ovary when taken before ovulation. They may also prevent sperm and egg from uniting or stop a fertilized egg from attaching to the uterus. The two ECP regimens discussed in these guidelines do not interfere with an established pregnancy.

### Effectiveness

Various studies have shown that the levonorgestrel-only regimen reduces the risk of pregnancy by 60 percent to 93 percent or more after a single act of intercourse, and

the combined regimen reduces it by 56 percent to 89 percent. In direct comparisons, the levonorgestrel regimen has been shown to be substantially more effective than the combined regimen. Both regimens appear to be more effective the sooner after intercourse they are used. ECPs are not as effective as consistent and correct use of most modern contraceptive methods.

### Side Effects

Side effects of both regimens include nausea, vomiting, abdominal pain, fatigue, headache, dizziness, breast tenderness, and irregular vaginal spotting or bleeding. The levonorgestrel-only regimen is associated with a significantly lower chance of nausea and vomiting than the combined regimen. In most women, menses following treatment will occur within a week before or after the expected time.

### Prevention and Management of Nausea and Vomiting

The best way to minimize nausea and vomiting is to use the levonorgestrel-only regimen instead of the combined regimen whenever possible. Pretreatment with the antiemetic drugs meclizine or metoclopramide can prevent these symptoms in users of the combined regimen. If vomiting occurs within two hours after either dose, repeat the dose, if feasible. In cases of severe vomiting, vaginal administration of ECPs may be effective.

### Precautions

There are no known medical conditions that preclude the use of ECPs. ECPs are not indicated in women with confirmed pregnancy because they will have no effect. However, ECPs may be given without pregnancy testing or when pregnancy status is unclear, as there is no evidence suggesting harm to a pregnant woman or to her pregnancy.

### Screening

Because ECPs are not dangerous under any known circumstances, routine screening via examination or laboratory tests is unnecessary prior to treatment. The client herself can determine whether ECPs are indicated after written or oral instruction. A pregnancy test may be helpful in ruling out pregnancy if the client has missed a menstrual period. However, treatment should not be delayed in order to perform any screening procedures.

## Special Situations

- **Breastfeeding:** There is no evidence that ECPs will harm a breastfeeding woman or her infant, although some authorities recommend feeding immediately before taking the pills and then expressing and discarding the breast milk for the six hours afterwards.
- **Coital act(s) more than 120 hours in the past:** ECPs may be used, but clients should be informed that efficacy has not been studied. Emergency intrauterine device (IUD) insertion should be considered.
- **More than one prior unprotected act:** One ECP treatment may be used to cover all unprotected or inadequately protected acts within the past 120 hours.
- **Repeated ECP use:** ECPs may be used as frequently as requested, but clients should be informed that ongoing, correct use of other contraceptive methods provides more effective protection over time.
- **Use of ECPs before intercourse:** No data are available on how long the contraceptive effect of ECPs persists after the pills have been taken. Clients should be encouraged to use a contraceptive method other than ECPs whenever possible.
- **Unprotected intercourse during the “infertile period”:** Because it is often difficult to define the infertile period with certainty, ECPs are recommended any time that unprotected or inadequately protected intercourse occurs and the client is concerned that she is at risk for pregnancy.
- **Concurrent use of other drugs:** Clients should be counseled about the possibility of drug interactions and managed accordingly (see Section 2.7).
- **Use of other formulations:** Combined estrogen-progestin pill formulations containing the progestin norethindrone in place of levonorgestrel can be used when the regimens described herein are not available.

## Information for Clients

Information about ECPs and related issues may be provided in person, over the telephone, in writing, or by a combination of these approaches. At a minimum, the following messages should be conveyed:

- The client should start treatment as soon as possible after intercourse.
- Following ECP use, if the client’s menstrual period has not come within a week after it was expected, she should seek evaluation and care for possible pregnancy.
- If the client has irregular bleeding and lower abdominal pain, she should contact a health care provider for possible evaluation for ectopic pregnancy.
- The client should use another form of contraception after using ECPs. ECPs are not suitable for ongoing contraception.
- ECPs do not protect against HIV or other sexually transmitted infections (STIs).

Ideally, the client should also be given information about efficacy, side effects, mechanism of action, other contraceptive methods, and methods to prevent STIs. She should be offered a temporary method, such as condoms, for use in the immediate future, and referrals to facilities where she can obtain any needed follow-up services. All counseling should be nonjudgmental and supportive.

## Follow-up

Advise the client to see a health care provider if she experiences irregular bleeding combined with lower abdominal pain or if she has any questions or reason for concern.



# EMERGENCY CONTRACEPTIVE PILLS: MEDICAL AND SERVICE DELIVERY GUIDELINES

## 1 Introduction

Despite the availability of highly effective methods of contraception, many pregnancies are unplanned and unwanted. These pregnancies carry a higher risk of morbidity and mortality, often due to unsafe abortion. Many of these unplanned pregnancies can be avoided using emergency contraception.<sup>1,2</sup>

### 1.1 Definition

Emergency contraceptive pills (ECPs) are hormonal methods of contraception that can be used to prevent pregnancy after an unprotected or inadequately protected act of intercourse.

ECPs sometimes are referred to as “morning-after” or “postcoital” pills. The term “emergency contraceptive pills” is preferred because it conveys the important message that the treatment should not be used as an ongoing contraceptive method, and it avoids giving the mistaken impression that the pills must be taken on the morning after intercourse.

These guidelines address medical and service delivery issues related to two regimens of ECPs, one containing a progestin only (levonorgestrel), and the other containing a combination of a progestin (levonorgestrel) and an estrogen (ethinyl estradiol).

A brief overview of the use of intrauterine devices (IUDs) for emergency contraception is included in the Appendix.

### 1.2 Indications

ECPs are indicated to prevent pregnancy after unprotected or inadequately protected sexual intercourse, including:

- when no contraceptive has been used;
- when there is a contraceptive failure or incorrect use, including:
  - condom breakage, slippage, or incorrect use
  - two or more consecutive missed combined oral contraceptive pills
  - progestin-only pill (minipill) taken more than three hours late
  - more than two weeks late for a progestin-only contraceptive injection (depot-medroxyprogesterone acetate or norethisterone enanthate)
  - more than seven days late for a combined estrogen-plus-progestin monthly injection
  - dislodgment, delay in placing, or early removal of a contraceptive hormonal skin patch or ring
  - dislodgment, breakage, tearing, or early removal of a diaphragm or cap
  - failed coitus interruptus (e.g., ejaculation in vagina or on external genitalia)
  - failure of a spermicide tablet or film to melt before intercourse
  - miscalculation of the periodic abstinence method or failure to abstain on fertile day of cycle
  - IUD expulsion; or
- in cases of sexual assault when the woman was not protected by an effective contraceptive method.

## 2 Emergency Contraceptive Pills

### 2.1 ECP Regimens

Two ECP regimens are discussed in these guidelines:

- **Levonorgestrel-only regimen:** 1.50 mg levonorgestrel in a single dose or in two doses of 0.75 mg taken up to 12 hours apart.
- **Combined estrogen-progestin (Yuzpe) regimen:** two doses of 100 mcg ethinyl estradiol plus 0.50 mg of levonorgestrel taken 12 hours apart.

Note that levonorgestrel plus an equal amount of a related but inactive compound is called norgestrel; therefore, these regimens can also be formulated by substituting double the amount of norgestrel as is indicated for levonorgestrel.

Treatment with either regimen should be initiated as soon as possible after unprotected or inadequately protected intercourse, because efficacy declines substantially with time.<sup>3,4</sup> Early data showed that both regimens are effective when used up to 72 hours after intercourse.<sup>5,6</sup> Consequently, some product package instructions and older guidelines advise use only within that time frame. However, more recent studies indicate that the regimens continue to be moderately effective if started between 72 and 120 hours.<sup>4,7</sup> No data are available on efficacy if treatment is started more than 120 hours after intercourse.

Both regimens are available in some locations as products formulated and labeled specifically for use as

ECPs. They also can be made up from a variety of regular oral contraceptive pills (see Table 1 or [www.cccinfo.org](http://www.cccinfo.org)). The levonorgestrel-only regimen is preferred because it is more effective and is associated with a lower risk of nausea and vomiting.<sup>5</sup>

## 2.2 Mode of Action

Like all hormonal contraceptives, ECPs may work in a variety of ways. The precise mechanism of action of ECPs in a particular case cannot be determined and probably depends on the time in a woman's menstrual cycle when intercourse occurred and when ECPs were taken.<sup>8,9</sup> Several studies have provided direct evidence that when taken before ovulation, both the combined regimen and the levonorgestrel regimen can act by preventing or delaying ovulation.<sup>10-14</sup> 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.<sup>6,14,15</sup> However, other studies have shown no such effects with both the combined and levonorgestrel-only regimens,<sup>10,11,13,16,17</sup> and it is not clear that the observed changes would be sufficient to prevent implantation. Additional possible mechanisms include interference with sperm transport or penetration<sup>18,19</sup> and interference with corpus luteum function.<sup>14,20</sup> To date, no direct clinical data exist regarding these possibilities. Nevertheless, statistical evidence on the effectiveness of ECPs suggests that they could not be as effective as data indicate if they only worked by interfering with ovulation.<sup>21</sup>

ECPs have often been confused with medical abortion. ECPs are effective only in the first few days following intercourse before a pregnancy is established, while medical abortion is a nonsurgical option for terminating a pregnancy. At least five days elapse between intercourse and the establishment of a pregnancy, defined as implantation of a fertilized egg in the lining of a woman's uterus. ECPs work in this interval to prevent pregnancy. They are ineffective once implantation has begun. Data from studies of high-dose oral contraceptives indicate that neither of the two ECP regimens discussed here will interrupt an established pregnancy or harm a developing embryo.<sup>22</sup>

## 2.3 Efficacy

The statistic commonly used to express the efficacy of most contraceptive methods indicates the proportion of women who become pregnant while using the method over a fairly long period of time. This statistic is not meaningful for ECPs, which are intended for one-time use. Instead, the contraceptive efficacy of ECPs is commonly expressed in terms of the "prevented fraction," which is the proportion of

expected pregnancies averted by the treatment. Determining this fraction is not straightforward; it involves many assumptions that are difficult to validate. Therefore, the reported efficacy figures presented below may not be precise. Yet, precise estimates of efficacy may not be highly relevant to many women who have had unprotected intercourse, since ECPs are often the only available treatment. A more important consideration for most ECP clients may be the fact that ECPs (specifically, the levonorgestrel regimen) are certainly more effective than nothing.<sup>23</sup>

Four studies of the levonorgestrel regimen that included a total of almost 5,000 women reported prevented fractions between 60 percent and 93 percent; that is, this regimen reduced a woman's chance of pregnancy by that amount.<sup>4,5,24,25</sup> A meta-analysis of eight studies of the combined regimen including more than 3,800 women concluded that the regimen prevents about 74 percent of expected pregnancies; the proportion ranged from 56 percent to 89 percent in the different studies.<sup>26</sup> A large randomized trial that directly compared the two regimens showed that the levonorgestrel regimen is significantly more effective than the combined regimen. The relative risk of pregnancy in this study was 0.36, indicating that the chance of pregnancy among women who received the levonorgestrel regimen was about one third of the chance among those who received the combined regimen.<sup>5</sup>

Multiple studies have indicated that both regimens are more effective the sooner after intercourse the pills are taken.<sup>4,5,25,27</sup> Some older studies of the combined regimen did not show this time effect,<sup>28</sup> but they may not have been as rigorously conducted as more recent research. No data are available establishing efficacy if ECPs are taken more than 120 hours after intercourse.

ECPs are inappropriate for regular use as an ongoing contraceptive method for several reasons. First, ECPs are less effective than most modern methods over the long term. The prevented fraction statistic used to express efficacy of ECPs after a single use cannot be directly compared to published failure rates of other contraceptives used for prolonged periods of time. However, if ECPs were used as an ongoing method, the cumulative risk of pregnancy during a full year of use would likely be higher than the risk associated with regular hormonal contraceptives, male condoms, and other barrier methods. In addition, very frequent ECP use would result in more side effects (such as menstrual irregularities) and exposure to a higher total hormone dose than would regular use of either combined oral contraceptive pills or progestin-only pills. Data are not available on the incidence of medical complications (if any) in women who use current regimens of ECPs frequently over a long period of time.

## 2.4 Side Effects, Prevention, and Management

No deaths or serious complications have been causally linked to emergency contraception.<sup>29</sup> Side effects that are medically minor but troublesome to clients do occur, however.

### *Nausea and vomiting*

Nausea occurs in about 18 percent of women and vomiting occurs in about 4 percent of women using levonorgestrel-only ECPs.<sup>4,5,24,25</sup> Nausea and vomiting occur in about 43 percent and 16 percent, respectively, of clients using the combined regimen.<sup>30</sup> In studies directly comparing the two regimens, the levonorgestrel regimen has been shown to cause significantly and substantially less nausea and vomiting than the combined regimen.<sup>5,25</sup> If they occur, these symptoms are usually limited to the first three days after treatment.<sup>31</sup>

#### **Prevention**

The best way to minimize nausea and vomiting is to use the levonorgestrel-only regimen instead of the combined regimen whenever possible. Nausea and vomiting are uncommon enough with the levonorgestrel-only regimen that prophylactic administration of an antiemetic drug is not routinely warranted. However, if the combined regimen is used, antiemetic pretreatment may be considered, depending on program and client resources. A single dose of meclizine (50 mg), taken one hour before the first dose of the regimen, reduces the risk of nausea by about 30 percent and the incidence of vomiting by about 60 percent. Clients who use meclizine should be warned that it might cause drowsiness.<sup>30</sup> Metoclopramide, 10 mg taken one hour before each dose of the combined regimen, also reduces the incidence of nausea.<sup>32</sup> Lower doses of these drugs and other antiemetics also may prevent nausea and vomiting, but they have not been studied. It is not possible to predict which ECP users will have nausea or vomiting or which women will benefit from antiemetic pretreatment. Taking ECPs with food has not been shown to alter the risk of nausea.<sup>30,33</sup>

#### **Management**

If vomiting occurs within two hours of taking an ECP dose, many experts believe that the dose should be repeated. In cases of severe vomiting, ECPs can be administered vaginally. Studies of regular oral contraceptive pills administered by this route suggest that the hormones are well absorbed through the vaginal mucosa.<sup>34,35</sup>

### *Delay in menses*

Clients should be informed that ECPs do not necessarily bring on menses immediately (a potential mispercep-

tion among ECP users); the menstrual period usually occurs within one week before or after the expected time.

#### **Management**

After using ECPs, if the menstrual period has not come by a week after it was expected, the client should be advised to consider the possibility that she may be pregnant and to seek appropriate evaluation (such as a pregnancy test) and care.

### *Irregular vaginal bleeding*

Some women may experience irregular bleeding or spotting after taking ECPs. The proportion with this side effect varies substantially in different studies; for example, trials of the LNG regimen found that between 0 percent and 17 percent of women reported non-menstrual bleeding in the first week after use.

#### **Management**

Irregular bleeding due to ECPs is not dangerous and will resolve without treatment. However, it is important not to discount the possibility that irregular bleeding after ECP use may be due to another more serious cause, such as ectopic pregnancy. Consideration should be given to evaluating this symptom with a pregnancy test and other appropriate tests if the woman has other symptoms of ectopic pregnancy, such as lower abdominal pain.

### *Other side effects of ECPs*

Other side effects may include abdominal pain, breast tenderness, headache, dizziness, and fatigue. These side effects usually do not occur more than a few days after treatment, and they generally resolve within 24 hours.<sup>31</sup>

#### **Management**

A nonprescription pain reliever can be used to reduce discomfort due to headaches or breast tenderness.

### *Effects on pregnancy*

Results from studies of high-dose oral contraceptives suggest that neither the pregnant woman nor the fetus will be harmed if ECPs are inadvertently used during early pregnancy.<sup>36</sup> Available evidence suggests that ECPs do not increase the chance that a pregnancy following ECP use will be ectopic; in fact, like all contraceptive methods, ECPs reduce the absolute risk of ectopic pregnancy by preventing pregnancy in general.<sup>37</sup>

## 2.5 Precautions

No evidence exists to indicate that ECPs are dangerous under any known circumstances or in women with any particular medical condition. Although some product

package inserts list precautions similar to those associated with continuous use of combined oral contraceptives and levonorgestrel-only pills, experts believe that these precautions do not apply to ECPs because the treatment is so short. Women with previous ectopic pregnancy may use ECPs.

ECPs are not indicated for a woman who has a confirmed pregnancy because they will have no effect. However, if an evaluation for pregnancy has not been performed or if pregnancy status is unclear, ECPs may be provided, as there is no evidence suggesting harm to the woman or to an existing pregnancy. In the absence of pregnancy evaluation, though, the client should understand that she could already be pregnant, in which case ECP treatment will not be effective.

## 2.6 Screening

Because ECPs are safe for all women, and clients can determine for themselves whether they have had unprotected or inadequately protected intercourse, the only purpose of screening is to identify situations when ECPs are clearly not needed (e.g., the client is already pregnant) or when an emergency contraceptive treatment other than ECPs (i.e., an IUD) should be considered. This screening can be done by a clinician or other trained provider or by the client herself after written or oral instruction.<sup>38</sup> Clinical assessments (e.g., pregnancy test, blood pressure measurement, laboratory tests, pelvic exam) are not required but can be offered if medically indicated for other reasons and desired by the client. A pregnancy test may be helpful in detecting pregnancy if the client has missed a menstrual period.

ECPs should not be withheld or delayed in order to carry out screening procedures.

## 2.7 Special Issues

### *Use in breastfeeding women*

A woman who is less than six months postpartum, is exclusively breastfeeding, and has not had a menstrual period since delivery is unlikely to be ovulatory and therefore is unlikely to need ECPs. However, a woman who is providing supplemental feeding to her infant or who has had menses since delivery may be at risk for pregnancy. A single treatment with ECPs is unlikely to have an important effect on milk quantity or quality. An unknown amount of hormone may pass into the breast milk. Some authorities recommend that nursing women should feed the baby immediately before taking ECPs and then express and discard the breast milk for the next six hours, but the need for this practice is not proven.

### *Use after coital act(s) more than 120 hours in the past*

No data are available on efficacy if treatment is started more than 120 hours after intercourse. However, since ECPs apparently pose no danger either to the woman or to the embryo if the ECPs fail, it is reasonable to provide them if the client is fully counseled about the possibility of pregnancy. A more effective approach would be to insert a copper IUD (see Appendix), if the earliest unprotected act occurred within the past seven days and the woman is otherwise a candidate for emergency IUD insertion.

### *Use after more than one unprotected act*

ECPs should not be withheld if the client has had more than one unprotected or inadequately protected act of intercourse, unless she is known to be already pregnant. However, clients should be informed that the efficacy of the ECPs will decline as the interval between the earliest coital act and the use of the ECPs lengthens. Clients should be encouraged to use ECPs as promptly as possible after an act of unprotected intercourse and not to wait until they have had a series of unprotected acts. Only one ECP treatment should be given at a time, regardless of the number of prior unprotected acts.

### *Repeated use*

ECPs are not intended for repeated use (see Section 2.3) and no direct data are available about the effects of frequent use of current regimens. However, experience with similar regimens<sup>39</sup> and with high-dose oral contraceptives suggests that the likelihood of harm from limited repeat use is low. ECPs should not be denied just because the woman has used them before, even within the same menstrual cycle. All women who use ECPs, especially those who use them repeatedly, should be given information about other forms of contraception and counseling about how to avoid future contraceptive failures. Certainly repeated use of ECPs is safer than pregnancy, in particular when the pregnancy is unintended and women do not have access to safe abortion services.

### *Use of ECPs before intercourse*

No data are available about how long the contraceptive effect of ECPs persists after the pills have been taken. Presumably ECPs taken immediately before intercourse are as effective as ECPs taken immediately afterwards. However, if a woman has the opportunity to plan to use a contraceptive method before intercourse, a method other than ECPs, such as condoms or another barrier method, is recommended.



### *Use of ECPs during the “infertile period”*

Studies have shown that fertilization can result from intercourse only during a five- to seven-day interval around the time of ovulation.<sup>40</sup> Theoretically, ECPs should not be needed if unprotected intercourse occurs at other times of the cycle, because the chance of pregnancy even without ECPs would be zero. However, in practice, it is often impossible to determine for certain whether a specific act of intercourse occurred on a fertile or infertile cycle day. Therefore, ECPs generally should be provided any time unprotected or inadequately protected intercourse occurs and the client is concerned that she is at risk for pregnancy. In situations when the unprotected act is extremely unlikely to result in pregnancy, the client’s anxiety level and the availability of program and client resources should be taken into account in making the decision.

### *Drug interactions*

No specific data are available about the interactions of ECPs with other drugs that the client may be taking. However, it seems reasonable that drug interactions would be similar to those with regular oral contraceptive pills. A full discussion of this matter is beyond the scope of these guidelines, but several excellent references on the subject are available.<sup>41-45</sup> Women taking drugs that may reduce the efficacy of oral contraceptives (including but not limited to rifampicin, certain anticonvulsant drugs, and Saint John’s wort) should be advised that the efficacy of ECPs may be reduced. Consideration may be given to increasing the amount of hormone administered in the ECPs, either by increasing the amount of hormone in one or both doses, or by giving an extra dose.

### *Use of other formulations*

One study has shown that a combined estrogen-progestin pill formulation containing the progestin norethindrone offered an efficacy and side effect profile similar to the standard combined pill regimen containing levonorgestrel.<sup>33</sup> These results suggest that oral contraceptive pills containing progestins other than levonorgestrel may be used for emergency contraception in situations when the two standard regimens are not available.

## **2.8 Information for the Client**

Relevant information can be provided to ECP clients in person, over the telephone, in writing (e.g., in a pamphlet or product package insert), or by a combination of these methods. This information should include at least the following key messages:

- The client should take ECPs as soon as possible after intercourse to maximize efficacy. She should not take extra doses unless she vomits within two hours after a dose.
- After taking ECPs, if the next menstrual period has not come by a week after it was expected, the client should consider the possibility that she may be pregnant and seek evaluation and care.
- If the client has irregular bleeding and lower abdominal pain, she should contact a health care provider for possible evaluation of ectopic pregnancy.
- ECPs are not suitable for ongoing contraception. The client should use a standard method of contraception to prevent pregnancy from coital acts in the future.
- ECPs do not protect against HIV or other sexually transmitted infections (STIs). The act of intercourse that prompted the request for ECPs may have put the client at risk for these infections, and she should consider getting tested.

Ideally, the client should also be given information about efficacy, side effects, and mechanism of action of ECPs, as well as information about other contraceptive methods to use in the future and methods for preventing STIs. Whenever feasible, a regular method such as condoms should be offered for her to use in the immediate future. Depending on the situation, the client should be referred to facilities where she can obtain pregnancy care in case of treatment failure, tests for STIs and HIV, and other needed services.

However, clients should not be overwhelmed with so much information that they cannot absorb it all. In addition, some clients may not want counseling on certain topics (such as information on other contraceptive methods or on the mechanism of action of ECPs) at the time they receive ECPs. Providers should not deny ECPs to women who refuse more than the minimum information needed to ensure that they use ECPs correctly.

## **2.9 Counseling**

Two studies have suggested that most women do not need any interaction with a health care provider in order to use ECPs safely and effectively.<sup>38,46</sup> However, counseling can serve to reinforce any messages given in writing and may lead to better overall outcomes. Counselors should be mindful of possible unique sources of anxiety among women requesting ECPs: embarrassment at failing to use contraception effectively; rape-related trauma; concern about STIs, including HIV, due to condom failure or non-use; and hesitation due to a misperception that ECPs cause abortion.

Counselors should be as supportive as possible of the client's choices and refrain from making judgmental comments or indicating disapproval through body language or facial expressions while discussing ECPs with clients. Supportive attitudes will help set the stage for follow-up counseling about regular contraceptive use and prevention of STIs. When possible, give clients written as well as oral instructions for taking the ECPs. Pictorial instructions may help clients whose literacy may be limited.

Actively involving the client in the counseling process is encouraged. For example, a provider might ask her what she has heard about ECPs, discuss her experience with other contraceptive methods (particularly the incident that led to the ECP request), and explore her current approach to protecting herself from STIs. Validating or correcting her ideas as appropriate may be more effective in ensuring compliance than simply providing her with information.

Whenever possible, ensure that counseling is conducted in private. In situations where privacy is inadequate (for instance, in many pharmacies), advise clients to contact a health care or family planning provider for additional information and counseling about regular contraceptive methods. Reassure all clients, regardless of age or marital status, that all information that they give to the provider, as well as the fact that they have received treatment, will be kept confidential.

## 2.10 Follow-up

No scheduled follow-up is required after ECP use unless the client identifies a problem or question. However, the client should be advised to seek follow-up care if she:

- needs ongoing contraceptive counseling or a contraceptive method;
- has not had a menstrual period by a week after it was expected;
- has irregular bleeding and lower abdominal pain;
- suspects she may be pregnant;
- needs other services, such as evaluation for STIs; or
- has other reasons for concern.

## 2.11 If the Client Becomes Pregnant

A woman who has used ECPs may later find herself to be pregnant because the ECPs have failed, because she was already pregnant before taking the ECPs, or because coital acts after taking the ECPs led to pregnancy. In any of these cases:

- Advise the client about all available options, and let her decide which is most appropriate for her situation.

Respect and support her decision. Refer her to other service providers as appropriate.

- If she decides to continue the pregnancy, reassure her that there is no evidence of any teratogenic effect following ECP use. Available data suggest that ECPs do not increase the likelihood that a subsequent pregnancy will be ectopic.

## 2.12 Starting or Resuming Regular Contraception after ECP Use

Whenever possible, clients receiving ECPs should be given contraceptive counseling and provided with an ongoing contraceptive method, such as condoms, for at least immediate future use. However, such counseling may not be appropriate in all situations or may not be desired by clients at the time of ECP provision, and it should not be a prerequisite for providing ECP services. Clients who need or desire counseling but who do not receive it at the ECP visit should be referred for a follow-up appointment at the earliest convenient time.

Clients may wish to restart their previous contraceptive method after taking ECPs, or they may prefer to initiate a new method. If the reason for requesting ECPs is because the regular contraceptive method failed (for example, the condom broke or the client missed taking oral contraceptive pills), discuss with the client the reasons for failure and how it can be prevented in the future. In some cases, the need for ECPs may be an indication that a change of methods should be considered.

ECP clients, particularly those with risk factors for STIs, such as young age, multiple partners, or residence in a location where STIs are especially prevalent, should ideally receive counseling on how to prevent STIs as well as pregnancy by using condoms in addition to or as the primary contraceptive method.

### *Guidelines for initiating or restarting contraceptive use after using ECPs*

#### **Male or female condom**

Can be used immediately.

#### **Diaphragm or cervical cap**

Can be used immediately.

#### **Spermicidal foam, tablets, jelly, cream, or film**

Can be used immediately.

### **Oral contraceptives, hormonal contraceptive patch, or vaginal ring**

Two options are offered. Many experts recommend the first as preferable because the method is initiated sooner, which may reduce subsequent pregnancy risk.

**a. The client may begin using the method the day after taking the ECPs.** If she is newly starting the method, she should begin with a new pill pack, patch, or ring. If she was previously using the method (e.g., the ECPs were indicated because of missed pills or dislodgement of the patch or ring), she may resume using the pill pack, patch, or ring that she was previously using. In this case, she should be reminded that the patch or ring will not be effective past the original date on which it was scheduled to be removed. All clients starting hormonal methods immediately after using ECPs should use a barrier method if they have intercourse in the next seven days after starting or restarting the method. Clients may have some irregular bleeding until the onset of menses.

**b. The client may wait until the beginning of her next menstrual cycle and then start the method according to the standard instructions for that method.** In this case, she should be advised to use a barrier contraceptive method or abstain from intercourse for the remainder of the current cycle.

### **Injectables**

Initiate progestin-only injectables and combined monthly injectables within seven days after the beginning of the next menstrual cycle. The client should use a barrier contraceptive or abstain from intercourse until she receives the injection.

### **Implants**

Insert within seven days after the beginning of the next menstrual cycle. Use a backup method or abstain from intercourse until the implants are inserted.

### **IUD**

Insert after the start of the next normal menstrual period. The client should use a barrier contraceptive or abstain from intercourse until the IUD is inserted.

NOTE: If the client intends to use an IUD as a long-term method and meets IUD screening criteria, emergency insertion of a copper-bearing IUD may be a good alternative to ECP use (see Appendix).

### **Natural family planning**

Natural family planning may be initiated after the first normal menstrual period following ECP use. If

intercourse occurs in the interim, an alternate contraceptive method (such as condoms) or abstinence should be used.

### **Female or male sterilization**

Perform the operation only after informed consent can be ensured. It is not recommended that clients make this decision under the stressful conditions that often surround ECP use. Defer female sterilization until after the client's first menstrual period, to ensure that she is not pregnant. Use a backup method or abstain from intercourse until the sterilization procedure is performed.

## **3 ECP Service Delivery Systems**

Given that ECPs appear to be most effective when taken soon after intercourse, every effort should be made to ensure that women know about ECPs before they need them. This can be accomplished by:

- routinely informing women about ECPs at the time of regular medical or family planning visits;
- including information about ECPs on Web sites or telephone answering machines;
- distributing written information about ECPs with other contraceptive supplies or medications;
- including information about ECPs within sexual education programs; or
- instituting mass-media informational campaigns and advertising ECP services.

Information about ECPs is particularly relevant to adolescents who are not yet sexually active; to women who are using contraceptive methods that are often used inconsistently or incorrectly, such as barrier methods, oral contraceptives, or natural family planning; and to other high-risk women, such as youth, migrant workers and their spouses, and victims of sexual assault.

It is also critical that women be able to obtain ECPs quickly when the need arises. Because the instructions for use of ECPs are simple and medical screening is not necessary, the requirement for an immediate visit to a doctor is not necessary for safe and effective use<sup>38</sup> and may create barriers to access. Some approaches to facilitating access are:

- providing women with an advance prescription or supply of ECPs;<sup>47</sup>
- prescribing ECPs by telephone without seeing the client;
- training nurses, midwives, pharmacists, or nonclinical individuals such as community health workers and

sexual assault counselors to provide ECPs, if allowed by local regulations;

- ensuring that nonclinical staff in health facilities, whom clients may contact before seeing a clinician, are aware of the availability of ECPs;
- distributing ECPs through nonclinical settings, such as through community-based services, schools, social marketing programs, and the commercial sector (e.g., pharmacies); or
- distributing ECPs over the counter.<sup>48</sup>

All ECP providers should be given appropriate training and follow clear service delivery guidelines. Training should include information on indications for ECP use, recommended ECP regimens, mode of action, efficacy, side effects and their management, precautions and screening, client information and counseling needs, and follow-up procedures. In addition, because ECPs are a backup method, the training also should include information about other contraceptive methods, if necessary for the audience. The training often is most effective if it is participatory in nature and includes exercises to build participant skills in the areas of screening, counseling, and follow-up. To obtain provider-training curricula, please contact the International Consortium for Emergency Contraception or visit the Consortium's Web site at [www.cccinfo.org](http://www.cccinfo.org).

### 3.1 Youth

Reaching adolescents with emergency contraceptive information and services poses special challenges to programs. Young women may find it difficult to access relevant information about or services for emergency contraception because they:

- are unaware of the availability of ECPs;
- lack confidence or are embarrassed to visit a family planning clinic;
- do not know of the existence of the clinic;
- find the clinic hours inconvenient;
- fear a pelvic examination; or
- are anxious about judgmental attitudes of the providers.

Programs should work to ensure that clinics serving adolescents are youth-friendly (for example, by ensuring privacy and confidentiality, accessible facilities, reasonably priced services, and flexible hours — particularly during evenings and weekends).

### 3.2 Women Who Have Been Sexually Assaulted

Reaching women who have been forced to have intercourse also poses special challenges. ECP providers should be attentive to the possibility that these women may be:

- unaware that something can be done to prevent pregnancy after sexual assault;
- unwilling to report the assault and therefore unwilling to seek services;
- concerned they will be blamed for the assault by the medical provider; or
- also in need of diagnosis and treatment for STIs.

Program managers and providers should ensure that police stations, emergency health care centers, and other facilities where women may seek help after an assault can provide clients with ECPs, if appropriate, or at least with information about where to obtain ECPs and other needed treatments as promptly as possible.



**TABLE 1 ECP Formulations**

	Formulation (per pill)	Common Brand Names	Dose
<b>Levonorgestrel-only Regimen</b>	LNG 1.50 mg	(registrations pending)	1 tablet
	LNG 0.75 mg	Imediat N, Levonelle-2, NorLevo, Plan B, Post-day, Postinor-2, Vika, Vikela	2 tablets at once <b>OR</b> 1 tablet, followed by 1 more 12 hours later
<b>Combined Regimen</b>	EE 50 mcg + LNG 0.25 mg <b>OR</b> EE 50 mcg + NG 0.50 mg	E-Gen-C, Eugynon, Fertilan, Imediat, Neogynon, Nordiol, Ogestrel, Ovral, Ovrán, Preven, Tetragynon	2 tablets, followed by 2 more 12 hours later
	EE 20 mcg + LNG 0.10 mg	Alesse, Levlite, Aviane, Loette	5 tablets, followed by 5 more 12 hours later
	EE 30 mcg + LNG 0.15 mg <b>OR</b> EE 30 mcg + NG 0.30 mg	AnNa, Levlen, Levora, Lo/Femenal, Lo/Ovral, Low-Ogestrel, Microgynon 30, Nordette, Rigevidon	4 tablets, followed by 4 more 12 hours later

**Abbreviations:**

EE = Ethinyl Estradiol      LNG = Levonorgestrel      NG = Norgestrel

When using oral contraceptive pill packs containing 28 pills, the last seven pills should not be used. For all regimens, pills should be taken as soon as possible after intercourse but optimally within 120 hours.

**This table was prepared in October 2003. An updated table may be found on the Consortium Web site at: [www.cecinfo.org](http://www.cecinfo.org).**

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## APPENDIX: USE OF IUDS FOR EMERGENCY CONTRACEPTION

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Copper-bearing IUDs can be used as a method of emergency contraception. They are most appropriate for women in stable relationships who wish to retain the IUD for long-term contraception and who meet the screening requirements for regular IUD use. When inserted within seven days after intercourse, copper-bearing IUDs are the most effective method of emergency contraception; they reduce the risk of pregnancy by more than 99 percent.<sup>49,50</sup>

However, emergency IUD insertion requires a much higher degree of training and clinical oversight than administration of ECPs. Clients must be screened to exclude those who are already pregnant, those who have pelvic inflammatory disease or another reproductive tract

infection, and those who are at high risk for STIs. In many instances, the act of intercourse that led to the request for emergency contraception might put the woman at increased risk for STIs, in which case the IUD is not an optimal contraceptive choice.

For further information about use of IUDs for emergency contraception, consult the *IPPF Medical and Service Delivery Guidelines*. The most recent edition, which contains information about emergency contraception, is available from IPPF, Regent's College, Inner Circle, Regent's Park, London NW1 4NS, UK; Web site: [www.ippf.org](http://www.ippf.org).

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## ABOUT THE INTERNATIONAL CONSORTIUM FOR EMERGENCY CONTRACEPTION

The mission of the International Consortium for Emergency Contraception is to expand access to and ensure safe and locally appropriate use of emergency contraception worldwide within the broader context of family planning and reproductive health, with emphasis on developing countries.

The seven founding members of the Consortium initially focused on introducing a dedicated emergency contraceptive pill product in selected “demonstration” countries. As interest in emergency contraception and the Consortium grew, the Consortium expanded its membership to include a wide range of organizations working to ensure that women have access to all forms of emergency contraception. The specific objectives of the Consortium are to:

- ✿ serve as an authoritative source of information about emergency contraception;
- ✿ be a voice for expanded access to and safe and appropriate use of emergency contraception;
- ✿ serve as a strategic planning forum for emergency contraception service delivery and information, education, and communication efforts;
- ✿ facilitate information sharing and networking among Consortium members and other groups working to broaden knowledge of and access to emergency contraception;
- ✿ encourage partnerships between public-sector organizations and private industry that are designed to make high-quality products for emergency contraception for large numbers of women worldwide at an affordable price; and
- ✿ seek and promote new emergency contraceptive methods that are safe and effective.

The Consortium welcomes applications for membership from noncommercial agencies that share the Consortium’s overall goal of expanding access to emergency contraceptive products and services in developing countries. Interested applicants should contact the Consortium Coordinator. The Consortium and the American Society for Emergency Contraception also jointly produce an electronic

update of emergency contraception activities worldwide. If you would like to subscribe or contribute an article to this update, please contact the Consortium at the following address or the American Society for Emergency Contraception at [Amsocce@aol.com](mailto:Amsocce@aol.com).

Consortium Coordinator  
International Consortium for Emergency Contraception  
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Web site: [www.cecinfo.org](http://www.cecinfo.org)

The International Consortium encourages the formation of regional networks or consortia in order to better address specific issues and local barriers to EC access. For information on these organizations, please contact the following addresses:

- ✿ **Africa:** EC Afrique. Web site: [www.ec-afrique.org](http://www.ec-afrique.org); E-mail: [ec-afrique@pcnairobi.org](mailto:ec-afrique@pcnairobi.org); Mail: ECafrique Secretariat, Population Council, PO Box 17643, 00500 Nairobi, Kenya.
- ✿ **Latin America:** Latin American Consortium for Emergency Contraception (LACEC)/Consortio Latinoamericano de Anticoncepcion de Emergencia (CLAE). Web site: [www.clae.info](http://www.clae.info); E-mail: [vschiappa@icmer.org](mailto:vschiappa@icmer.org); Mail: Instituto Chileno de Medicina Reproductiva (ICMER), Jose Victorino Lastarria 26, Depto. 21, Santiago, Chile.
- ✿ **Asia (Southeast):** Asia Pacific Network on Emergency Contraception (APNEC). Web site: N/A; E-mail: [equintillan@piwh.org](mailto:equintillan@piwh.org); Mail: Pacific Institute for Women’s Health, 3450 Wilshire Boulevard, Suite 1000, Los Angeles, CA 90010 USA.
- ✿ The Consortium maintains two listings of individuals and organizations working in the **Arab** and **East European/NIS/Balkan** regions. To join either region’s listserve, please e-mail the following addresses: Arab region: [arabregion@cecinfo.org](mailto:arabregion@cecinfo.org). East Europe, the Balkans, and the NIS region: [europeregion@cecinfo.org](mailto:europeregion@cecinfo.org). Additional information and updated contact information are available on the Consortium Web site: [www.cecinfo.org](http://www.cecinfo.org).





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## **INTERNATIONAL CONSORTIUM FOR EMERGENCY CONTRACEPTION**

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