# **Complete Summary**

### **GUIDELINE TITLE**

Emergency contraception.

## **BIBLIOGRAPHIC SOURCE(S)**

American Academy of Pediatrics. Emergency contraception. Pediatrics 2005 Oct;116(4):1026-35. [101 references] PubMed

## **GUIDELINE STATUS**

This is the current release of the guideline.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

## **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

## SCOPE

## **DISEASE/CONDITION(S)**

Unintended pregnancy

## **GUIDELINE CATEGORY**

Prevention

## **CLINICAL SPECIALTY**

Family Practice
Obstetrics and Gynecology
Pediatrics

#### **INTENDED USERS**

**Physicians** 

# **GUIDELINE OBJECTIVE(S)**

To provide pediatricians with a review of emergency contraception, including a definition of emergency contraception, formulations and potential adverse effects, efficacy and mechanisms of action, typical use, and safety issues, including contraindications

#### **TARGET POPULATION**

Adolescents

#### INTERVENTIONS AND PRACTICES CONSIDERED

## **Emergency contraception\* including:**

- 1. Products containing levonorgestrel only (including Plan B and others)
- 2. Products containing ethinyl estradiol + levonorgestrel (including Preven)

**\*Note**: "Emergency contraception" refers to the use of hormonal medications within 72 to 120 hours after unprotected or underprotected coitus for the prevention of unintended pregnancy.

## **General Management Strategies:**

- 1. Education and counseling about emergency contraception
- 2. Discussions concerning risk-avoidance/risk-reduction
- 3. Identification of a usual contraceptive method
- 4. Testing for sexually transmitted diseases
- 5. Advance prescriptions for emergency contraception
- 6. Concomitant treatment with an anti-emetic (i.e., meclizine or metoclopramide

## **MAJOR OUTCOMES CONSIDERED**

- Unintended pregnancy rates
- Adverse effects

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review

# **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

# RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

# **METHOD OF GUIDELINE VALIDATION**

Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not stated

## **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

# <u>Formulations of Emergency-Contraception Products and Potential</u> Adverse Effects

The formulations of emergency-contraception products used in the United States today include commonly available combination oral contraceptives (OCs) and the 2 dedicated products labeled for use as emergency contraception (Preven and Plan B) by the Food and Drug Administration (FDA) (see Table 1 of the original guideline document).

Please refer to the original guideline document for a discussion of combination OCs (estrogen-progestin).

## **Calculation of Dosing**

Each of the 2 doses taken must contain a minimum of 100 micrograms of ethinyl estradiol and a minimum of 0.50 mg of levonorgestrel. Levonorgestrel is the active isomer of norgestrel, so equivalent dosing of any pill containing norgestrel requires doubling the dose of progestin. Pill formulations used for emergency contraception are included in Table 1 of the original guideline document. Similar information may be obtained on certain Web sites, some of which are listed in Table 2 of the original guideline document.

Although the use of combination OCs has not been labeled specifically for emergency contraception, the FDA Reproductive Health Advisory Committee and professional organizations such as the American College of Obstetricians and Gynecologists have declared the use of combination OCs for emergency contraception safe and effective. The availability of many combination OCs with norgestrel or levonorgestrel makes this alternative particularly helpful when there is no or limited access to a dedicated emergency-contraception product.

# Nausea and Emesis with Emergency-Contraception Products Containing Estrogen

Nausea is experienced by approximately half and emesis by 17% to 22% of patients using estrogen-containing emergency-contraception methods, and these adverse effects seem unaffected by food intake. Other adverse effects might include fatigue, breast tenderness, headache, abdominal pain, and dizziness. Vomiting that occurs as a result of emergency contraception probably indicates that enough hormones have reached the bloodstream to have the desired contraceptive effect, but some experts, including the American College of Obstetricians and Gynecologists, recommend that if vomiting occurs within 30 to 60 minutes of taking an emergency-contraception product, a dose should be repeated. The severity and incidence of nausea and vomiting can be decreased significantly by using an antiemetic 1 hour before an estrogen-containing regimen. Antiemetics are ineffective if taken after nausea is present. An effective over-the-counter oral antiemetic is meclizine, 25 to 50 mg (Dramamine II), taken once before the combination-hormone methods. Patients should be counseled

about drowsiness as a possible adverse effect. A recent report suggests that metoclopramide (Reglan), 10 mg by mouth once, may also reduce the nausea and cramping associated with combination-hormone-containing pills.

## Preven (Combined Estrogen-Progestin)

Preven is a prepackaged dedicated product containing 50 micrograms of ethinyl estradiol and 0.25 mg of levonorgestrel in each tablet. To determine if a pregnancy is present from any unprotected contacts that occurred more than 10 days before, patients may use a urine pregnancy test included in the package. Instructions are to take 2 pills (100 micrograms ethinyl estradiol and 0.5 mg levonorgestrel per dose) at once and to repeat the dose of 2 pills in 12 hours. Because this combination-hormone-containing pill may cause nausea and vomiting, an antiemetic should be taken 1 hour before the first dose.

## Plan B (Progestin only)

Another available emergency-contraception product is Plan B, which contains 0.75 mg of levonorgestrel per pill. One pill is given per dose, 12 hours apart, although recent data suggest that both doses may be taken at the same time with similar effectiveness and no significant increase in adverse effects. This delivers a total treatment dose of 1.5 mg of levonorgestrel. This FDA-labeled method has several advantages over estrogen-progestin combination methods. There is significantly less nausea and vomiting in patients using Plan B compared with emergency-contraception formulations that contain estrogen. In addition, randomized, controlled trials have demonstrated that the use of Plan B results in even lower pregnancy rates than the combination estrogen-progestin methods.

## **Efficacy of Emergency Contraception**

Please refer to the original guideline document for a discussion on the efficacy of emergency contraception.

## **Mechanisms of Action of Emergency Contraception**

Please refer to the original guideline document for a discussion on the mechanisms of action of emergency contraception.

#### Typical Use of Emergency Contraception

Use of emergency contraception should be considered for those having had unprotected or inadequately protected coitus within the preceding 72 to 120 hours. Inadequate protection may include using broken or slipped condoms, missing 2 or more active oral contraceptive (OC) pills, being more than 2 weeks late for a depot medroxyprogesterone intramuscular injection, leaving the contraceptive patch off for more than 24 hours, or removing the contraceptive vaginal ring for more than 3 hours.

Progestin-only emergency contraception may be prescribed by telephone for a teen requesting emergency contraception for an unprotected sexual contact. A urine pregnancy test is not required before use of emergency contraception. The assessment for indication to treat may be done by obtaining a history. A question that might be used as telephone triage before suggesting or prescribing emergency contraception is outlined in the table below. A risk of pregnancy may be present on virtually any day of the cycle, because menstrual histories may be inaccurate and ovulation patterns may vary. A normal period should occur within 3 weeks of using emergency contraception. The discussion should include avoiding additional unprotected sexual contacts, particularly until a more reliable method of contraception can be initiated and/or maintained.

# Telephone Triage of Sexually Active Teens to Prescribe Emergency Contraception

- Have you had unprotected intercourse or had a problem or concern about your method of birth control during the last 3 to 5 days?
  - If the answer to the question is "yes," the patient may be a candidate for prescribing emergency contraception at that telephone visit.
  - For a telephone visit when emergency contraception is prescribed, the patient should be scheduled for a follow-up clinic evaluation for sexually transmitted diseases and pregnancy and for contraception within 10 to 14 days after taking emergency contraception.

Teens may not be able to give sufficiently adequate menstrual histories to exclude a preexisting pregnancy, and some teens already pregnant may try to use emergency contraception as an abortifacient. For patients seen in a clinical setting, the results of a urine pregnancy test are usually documented. If the test result is negative, a suggestion and prescription for emergency contraception should be given for any unprotected sexual contact or concern about regular contraception during the past 72 to 120 hours regardless of the patient's menstrual history. If telephone prescriptions for emergency contraception are made available for teens, then a scheduled office or clinic appointment should be made within 10 to 14 days after using emergency contraception to exclude an already existing pregnancy and/or to deal with issues of contraception and screening for sexually transmitted diseases. Confidential care addressing unprotected sexual contact and the need for emergency contraception should follow the same guidelines used to prescribe the more reliable methods of contraception. For rape or abuse victims when the assault was within the past 72 to 120 hours, emergency contraception should be offered in addition to collection of appropriate specimens, pregnancy testing, antibiotic prophylaxis, and counseling. For patients or families of patients making initial contact by telephone, prescribing emergency contraception should not be delayed and should be made available, and the young woman should be encouraged to seek medical care as soon as possible.

## Timing of Emergency Contraception

When indicated, teens need to be encouraged to initiate the proper use of emergency contraception. This encouragement might include the discussion of possible dating scenarios and the possible need for advance prescription of emergency contraception to encourage the correct use of contraception. Emergency contraception should be initiated as early as possible within 72 hours of the unprotected contact. The first and second emergency-contraception doses

should be taken 12 hours apart and at a time when compliance with the second dose is probable.

Please refer to the original guideline document for further information on the timing of emergency contraception.

## **Availability**

Dedicated products for emergency contraception may not be available in some pharmacies. Please refer to the original guideline document for more information on availability.

# Safety and Contraindications of Emergency Contraception

There are few absolute contraindications to the use of combination-hormone emergency contraception. There are no contraindications to progestin-only emergency contraception. The World Health Organization has stated that the only contraindication to the combination estrogen/progestin emergency-contraception method or the progestin-only emergency-contraception method is a known pregnancy, primarily because the treatment will not work if the patient is already pregnant. The overall risk of pregnancy is very low with appropriate use of emergency contraception. There have been sporadic case reports of ectopic pregnancies after the use of emergency contraception. Any patient with a history of salpingitis or ectopic pregnancy needs to be generally aware of the potentially increased risk of an ectopic pregnancy regardless of use or nonuse of emergency contraception. Although the data are inadequate, current studies do not support the conclusion that use of progestin-only emergency contraception increases the risk of ectopic pregnancy in the general population; in fact, it is protective by preventing pregnancy. A review of information suggests that there is no evidence demonstrating that any of the emergency-contraception methods are teratogenic. Evaluation of possible teratogenic effects of older, higher-dose OCs used on a daily basis in pregnancy has found no increased teratogenic risk. For chronic health conditions in which estrogen-containing OCs are contraindicated, combination emergency-contraception regimens may still be offered because the duration of use is extremely short. However, many providers prefer to prescribe progestin-only regimens for teens with known hypercoagulable states, such as a history of blood clots or hereditary hypercoagulopathies or thrombophilias. Because pregnancy may increase the risk of adverse outcomes in these health conditions, the contraceptive benefit and availability of combination emergency contraception may outweigh the risk of treatment. Evidence indicates the concurrent use of certain medications such as some antiepileptic drugs, St John's wort, medications to treat human immunodeficiency virus, the antibiotic rifampin, and the antifungal griseofulvin may reduce the efficacy of OCs and, thus, potentially the combination emergency contraception but not the progestin-only method of emergency contraception.

## Issues of Knowledge, Use, Access, and Availability

Please refer to the original guideline document for a discussion of studies related to the issues of knowledge, use, access, and availability of emergency contraception.

## Common Concerns about Emergency Contraception

The concern that widespread emergency-contraception use would encourage unprotected coitus in teens is not supported in the literature. Please refer to the original guideline document for a discussion of studies on this topic.

None of the methods of emergency contraception provide protection against sexually transmitted diseases. Patients who use emergency contraception should be encouraged to access a provider for counseling about and testing for sexually transmitted diseases. As a contraceptive, emergency contraception is not as effective as other regularly prescribed methods of birth control. Therefore, initiation of more effective hormonal contraception for teens planning on or likely to engage in continued sexual activity should also be encouraged.

Use of emergency contraception may slightly alter the menstrual pattern depending on the timing of the administration within the menstrual cycle. Approximately 98% of patients will menstruate within 3 weeks of treatment, with more than half menstruating at the expected time. If treatment is initiated before ovulation, the menses is often 3 to 7 days earlier than expected. Treatment initiated after ovulation usually results in menses at the expected time or in a slight delay. Patients who are 3 weeks posttreatment without menses should be evaluated for pregnancy.

## **Use of Emergency Contraception on College Campuses**

Use of emergency contraception on college campuses has the potential to decreases unintended pregnancy. Please refer to the original guideline document for further details on this topic.

## Advance Prescription and Provision of Emergency Contraception

Advance provision of a course of emergency contraception has been shown to be effective. Several studies have found that prescribing emergency contraception in advance increases the likelihood of young women's and teens' use of emergency contraception when needed, yet does not increase sexual or contraceptive risk-taking behavior compared with those receiving only education about emergency contraception.

The American College of Obstetricians and Gynecologists has promoted offering advance prescriptions for emergency contraception. As previously mentioned, potential regional barriers to access may exist in the United States, as documented in a recent survey of pharmacists in which 48% did not dispense emergency contraception. In other areas of the country, dispensing emergency contraception directly by pharmacists without a prescription has been successful in preserving teen access and privacy. Pediatricians should consider issues related to access and availability as part of teens' education about emergency contraception, which may include cost, transportation, knowledge about correct use, and dispensing sites.

## **Future of Emergency Contraception**

Emergency contraception has tremendous potential to reduce unintended pregnancy rates in teens and adults. Information on emergency contraception should be incorporated into the sexuality counseling included as part of a preventive health care visit. Emphasis should be on preventing unprotected coitus and assessing for other potential risk behaviors often associated with unprotected coitus such as alcohol use, substance abuse, date rape, and lack of parental supervision. Provision of medication or an advance prescription for emergency contraception should be considered.

Please refer to the original guideline document for further information on the future of emergency contraception.

## **Summary Statements**

- 1. Emergency contraception has the potential to further decrease the rate of unintended teen pregnancies in the United States.
- 2. Education and counseling about emergency contraception (*International Classification of Diseases, Ninth Revision*, code V25.03) should be a part of the annual preventive health care visit for all teen and young adult patients when sexuality issues are addressed.
- Education should address access and availability issues specific to each community, allowing access to emergency contraception within 72 to 120 hours of unprotected or inadequately protected coitus. Advance prescription for emergency contraception should be considered for teens and young adults.
- 4. Using the same hormones found in some oral contraceptives, emergency contraception acts primarily on the ovulatory process.
- 5. The controversy over the effects of emergency contraception on the endometrium and potential impact on implantation requires that physicians be knowledgeable about all potential mechanisms when offering it to patients and families to encourage more informed decision-making.
- Emergency contraception is not a teratogenic agent and does not have the ability to disrupt a pregnancy already implanted in the uterine lining.
   Emergency contraception should not be confused with the antiprogestin RU-486, or mifepristone.
- 7. The progestin-only method (Plan B) is better tolerated than the combination-hormone or Yuzpe method (Preven or oral contraceptives) and is more effective in preventing pregnancy. There are no medical contraindications to the use of progestin-only emergency contraception. Data suggest that both tablets of Plan B may be taken at the same time without affecting efficacy.
- 8. An increase in awareness and availability of emergency contraception to teens does not change reported rates of sexual activity or increase the frequency of unprotected intercourse among adolescents.
- 9. Patients who use emergency contraception should see their physician for risk-avoidance/risk-reduction discussions, identification of a usual contraceptive method, and testing for sexually transmitted diseases.
- 10. The American Academy of Pediatrics (AAP) continues to support improved availability of emergency contraception to teens and young adults, including over-the-counter access and limiting the barriers to access placed by some health care providers and venues.

## **CLINICAL ALGORITHM(S)**

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

- It is estimated that appropriate use of emergency contraception could reduce the number of unintended pregnancies each year by half and thereby similarly reduce the abortion rate.
- Increasing health care provider knowledge about emergency contraception has been demonstrated to increase the percentage of providers and the number of prescriptions written for emergency contraception.

#### **POTENTIAL HARMS**

- Nausea is experienced by approximately half and emesis by 17% to 22% of patients using estrogen-containing emergency-contraception methods, and these adverse effects seem unaffected by food intake. Other adverse effects might include fatigue, breast tenderness, headache, abdominal pain, and dizziness.
- Many providers prefer to prescribe progestin-only regimens for teens with known hypercoagulable states, such as a history of blood clots or hereditary hypercoagulopathies or thrombophilias. Because pregnancy may increase the risks of adverse outcomes in these health conditions, the contraceptive benefit and availability of combination emergency contraception may outweigh the risk of treatment. Evidence indicates the concurrent use of certain medications such as some antiepileptic drugs, St John's wort, medications to treat human immunodeficiency virus, the antibiotic rifampin, and the antifungal griseofulvin may reduce the efficacy of oral contraceptives and, thus, potentially the combination emergency contraception but not the progestin-only method of emergency contraception.

## **CONTRAINDICATIONS**

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The World Health Organization has stated that the only contraindication to the combination estrogen/progestin emergency-contraception method or the progestin-only emergency-contraception method is a known pregnancy, primarily because the treatment will not work if the patient is already pregnant.

## **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

Staying Healthy

## **IOM DOMAIN**

Effectiveness Patient-centeredness Timeliness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

American Academy of Pediatrics. Emergency contraception. Pediatrics 2005 Oct;116(4):1026-35. [101 references] <a href="PubMed">PubMed</a>

# **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## **DATE RELEASED**

2005 Oct

## **GUIDELINE DEVELOPER(S)**

American Academy of Pediatrics - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

American Academy of Pediatrics

## **GUIDELINE COMMITTEE**

Committee on Adolescence

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

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#### **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>American Academy of Pediatrics (AAP) Policy Web site</u>.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

### **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on November 22, 2005. The information was verified by the guideline developer on December 1, 2005.

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