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# Emergency Contraception

COMMITTEE ON ADOLESCENCE

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POLICY STATEMENT

# Emergency Contraception

## abstract

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Despite significant declines over the past 2 decades, the United States continues to have teen birth rates that are significantly higher than other industrialized nations. Use of emergency contraception can reduce the risk of pregnancy if used up to 120 hours after unprotected intercourse or contraceptive failure and is most effective if used in the first 24 hours. Indications for the use of emergency contraception include sexual assault, unprotected intercourse, condom breakage or slippage, and missed or late doses of hormonal contraceptives, including the oral contraceptive pill, contraceptive patch, contraceptive ring (ie, improper placement or loss/expulsion), and injectable contraception. Adolescents younger than 17 years must obtain a prescription from a physician to access emergency contraception in most states. In all states, females 17 years or older and males 18 years or older can obtain emergency contraception without a prescription. Adolescents are more likely to use emergency contraception if it has been prescribed in advance of need. The aim of this updated policy statement is to (1) educate pediatricians and other physicians on available emergency contraceptive methods; (2) provide current data on safety, efficacy, and use of emergency contraception in teenagers; and (3) encourage routine counseling and advance emergency-contraception prescription as 1 part of a public health strategy to reduce teen pregnancy. This policy focuses on pharmacologic methods of emergency contraception used within 120 hours of unprotected or underprotected coitus for the prevention of unintended pregnancy. Emergency contraceptive medications include products labeled and dedicated for use as emergency contraception by the US Food and Drug Administration (levonorgestrel and ulipristal) and the "off-label" use of combination oral contraceptives. *Pediatrics* 2012;130:1174–1182

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**KEY WORDS**

emergency contraception, adolescents, teen pregnancy, birth control, oral contraceptives

**ABBREVIATIONS**

FDA—US Food and Drug Administration
STI—sexually transmitted infection

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## BACKGROUND

Despite significant declines over the past 2 decades, the United States continues to have teen birth rates that are significantly higher than other industrialized nations.[1,2] The most recent birth data available indicate a birth rate of 34.3 per 1000 among 15- to 19-year-olds.[3] The most current pregnancy outcomes data indicate that 57% of teen pregnancies ended in live births, 27% ended in induced abortion, and 16% ended in miscarriage or stillbirth.[4,5] Pediatricians have an important role, through their interactions with adolescents, to address the major public health objective of continuing to reduce adolescent pregnancy in the United States.[6]

The current decrease in teen pregnancies since the 1990s has resulted from both increased abstinence and increased use of contraception,[7,8] but large numbers of teenagers continue to engage in unprotected sexual activity. The rate of "ever having intercourse" among 15- to 19-year-old females is 43%, and, among males of the same age range, this rate is 42%.[9] The rate increases between early and late adolescence, from 13% of 15-year-olds to 70% of 19-year-olds. Although most teenagers report first intercourse with a steady partner and consensual sex, approximately 10% report being forced to have sex. Rates of sexual assault among teenagers and young adults are higher than in any other group,[10] another factor increasing the risk of unintended pregnancy.[11]

Nearly 80% of pregnancies in adolescents are unintended[12] and result from contraceptive failure or nonuse. The most commonly used method of contraception reported by teenagers who have had intercourse is the condom, followed by withdrawal and the oral contraceptive pill.[9] Research has shown, however, that many teenagers use contraceptive methods inconsistently.[13] In addition to the risk of sexually transmitted infections (STIs), the pregnancy rate for withdrawal is particularly high (27% of women who use the withdrawal method will have an unintended pregnancy in the first year of using this method).[14] Although condoms are important for protection against STIs as well as pregnancy and the pill can be a very effective method for pregnancy prevention, both methods require strict adherence by the user to be maximally effective.

Emergency contraception can reduce the risk of pregnancy if used up to 120 hours after unprotected intercourse[15,16] or contraceptive failure and is most effective if used in the first 24 hours.[17,18]

In August 2007, the US Food and Drug Administration (FDA) authorized nonprescription access to Plan B (levonorgestrel, manufactured by Teva Women's Health, Woodcliff Lake, NJ) for women 18 years of age and older and then in 2009 changed the age limit to females 17 years of age and older. Prescription for emergency contraception is required for teenagers younger than 17 years in most states.[19] Male adolescents younger than 18 years are not able to buy Plan B either with or without a prescription, but they can buy Plan B if they are older than 18 years.

Studies have shown that adolescents are more likely to use emergency contraception if it has been prescribed in advance of need.[20] However, a majority of practicing pediatricians and pediatric residents do not routinely counsel patients about emergency contraception and have not prescribed it.[21–24] This policy statement will focus on pharmacologic methods of emergency contraception used within 120 hours of unprotected or underprotected coitus for the prevention of unintended pregnancy (Table 1).

## DEFINITION OF EMERGENCY CONTRACEPTION

Emergency contraception is the only contraceptive method designed to prevent pregnancy after intercourse. Indications for use of emergency contraception include sexual assault, unprotected vaginal sexual intercourse, and contraceptive failures, such as broken condoms and missed or late doses of other hormonal methods (ie, missing 3 consecutive doses of active birth control pills, patch off for more than 24 hours during 'patch-on' week, or vaginal ring out for more than 3 hours during 'ring-in' week). Emergency contraceptive medications include products labeled and approved for use as emergency contraception by the FDA (levonorgestrel and ulipristal acetate) and the "off-label" use of combination oral contraceptives—the Yuzpe method—described in the literature since 1974.[25] Pediatricians should also be aware that insertion of a copper intrauterine device within 5 days of unprotected intercourse is an additional method of emergency contraception available in the United States. This statement does not cover the intrauterine device method in more detail, because it is not an option available to most pediatricians in their offices.

## EMERGENCY-CONTRACEPTION METHODS

### Progestin-Only Regimens

Levonorgestrel emergency contraception was approved by the FDA in 1999 under the brand name Plan B and is currently marketed as Plan B, Plan B One Step (Teva Women's Health, Woodcliff Lake, NJ), and Next Choice (Watson Pharma Inc, Corona, CA). Plan B and Next Choice consist of 2 pills containing 0.75 mg of levonorgestrel each. Although prescribing directions indicate that patients should take each of the 2 pills 12 hours apart, recent data suggest that both pills taken together as a single dose (total treatment dose of 1.5 mg levonorgestrel) is equally effective and without increased adverse effect.[15] To this effect, the next generation of emergency contraception, Plan B One Step, is packaged as a single pill with 1.5 mg levonorgestrel to be taken 1 time.[26] Pharmacies may stock both 0.75-mg and 1.5-mg levonorgestrel versions. Package labeling indicates that all 3 brands of levonorgestrel emergency contraception should be taken within 72 hours of unprotected intercourse; however, data support that use up to 120 hours after intercourse may prevent pregnancy.[15,16]

**TABLE 1** Selected Regimens for Emergency Contraception Available in the United States[14,72]

| Brand | First Dose | Second Dose | Ethinyl Estradiol per Dose, μg | Levonorgestrel per Dose, mg |
|---|---|---|---|---|
| Progestin-only pills | | | | |
| Next Choice or Plan B | 2 pills | None | 0 | 1.5 |
| Plan B One-Step | 1 pill | None | 0 | 1.5 |
| Ovrette | 20 pills | 20 pill | 0 | 0.75 |
| Other emergency contraception | | | | |
| ella | 30 mg of ulipristal acetate | | | |
| Combined estrogen and progestin pills | | | | |
| Ovral | 2 white pills | 2 white pills | 100 | 0.5 |
| Levora | 4 white pills | 4 white pills | 120 | 0.6 |
| Nordette | 4 light orange pills | 4 light orange pills | 120 | 0.6 |
| Seasonale | 4 pink pills | 4 pink pills | 120 | 0.6 |
| Triphasil | 4 yellow pills | 4 yellow pills | 120 | 0.5 |
| Alesse | 5 pink pills | 5 pink pills | 120 | 0.5 |

Additional combinations are available at: http://ec.princeton.edu.

The FDA-labeled levonorgestrel methods are currently the preferred emergency contraception for teenagers because of their improved adverse effect profile and increased effectiveness in comparison with combination oral contraceptive methods. Adolescents should be instructed to take 1.5 mg of levonorgestrel as soon as possible and up to 120 hours after unprotected intercourse. No physical examination or pregnancy testing is required before use. Adolescents are advised to have a pregnancy test done if they do not have a normal period within 3 weeks of emergency-contraception use.

### Ulipristal Acetate Progesterone Agonist/Antagonist

In August 2010, the FDA approved a progesterone agonist/antagonist ulipristal acetate (ella, Watson Pharma Inc, Corona, CA) for use as an emergency contraceptive.[27] Ulipristal binds to the human progesterone receptor, thereby preventing the binding of progesterone. Ulipristal is a single pill containing 30 mg of ulipristal acetate and is indicated up to 120 hours after unprotected intercourse.[28] Unlike with hormonal emergency contraception, existing pregnancy must be excluded before prescribing ulipristal because of the risk of fetal loss if used in the first trimester of pregnancy.[28] Patients should be counseled that a pregnancy test is indicated if their period is more than 7 days later than expected after taking ulipristal. Patients should also be instructed to return for evaluation of the rare but possible occurrence of ectopic pregnancy if severe abdominal pain occurs 3 to 5 weeks after the dose. Ulipristal is available only by prescription regardless of age.

### Combined Hormonal Regimens (Yuzpe Method)

The use of combination oral contraceptives for emergency contraception is commonly referred to as the "Yuzpe method."[25] Commonly used since 1974, its acceptability and efficacy was limited by adverse effects of nausea and vomiting. The Yuzpe method involves taking 2 doses of pills, each containing a minimum of 100 μg of ethinyl estradiol and a minimum of 500 μg of levonorgestrel. Levonorgestrel is the active isomer of norgestrel, so equivalent dosing of any pill containing norgestrel requires doubling the dose of progestin. Other pill formulations used for emergency contraception are included in Table 1. Similar information is available from the Office of Population Research at Princeton University, which maintains a comprehensive source of information on emergency contraception (http://ec.princeton.edu/). The availability of many combination oral contraceptives with norgestrel or levonorgestrel makes this alternative particularly helpful when there is no or limited access to an emergency-contraception product. Although combination oral contraceptives have 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 oral contraceptives safe and effective for emergency contraception.[29,30]

## MECHANISM OF ACTION

Hormonal emergency contraception, including combined and progestin-only methods, inhibits ovulation, disrupts follicular development, and interferes with the maturation of the corpus luteum.[31–37] These are the same mechanisms by which other hormonal methods of contraception prevent pregnancy. Results of studies evaluating the effect of hormonal emergency contraception on the endometrium are conflicting. Some studies suggest that endometrial histologic or biochemical alterations occur after emergency contraception by which endometrial receptivity to the implantation of a fertilized egg is impaired.[31,38,39] Other studies demonstrate little to no effect on the endometrium.[32,33,35,37,40,41] Suggested mechanisms, including alteration of sperm or egg transport, interference with the fertilization process, and/or cervical mucus changes, have not been verified by clinical data.[42,43] Hormonal emergency

contraception does not interrupt established pregnancies and has not been linked to teratogenic effects.[44–47]

Ulipristal acetate inhibits follicular development and rupture, so its primary mechanism of action as an emergency contraceptive is considered to be inhibition or delay of ovulation.[28] It also decreases endometrial thickness and may have a direct effect on implantation. Ulipristal is in pregnancy category X, because data from animal studies suggest that fetal loss is a risk of use during the first trimester. Therefore, pregnancy should be excluded before a dose is given.

## EFFICACY

The efficacy of combined hormonal or progestin-only emergency contraception depends on the timing of use within the menstrual cycle.[48,49] A randomized controlled trial has shown that the progestin-only method, Plan B, is more effective at preventing pregnancy than combination hormone methods. When the 2 regimens were started within 72 hours, the overall pregnancy rate was 1.1% in the levonorgestrel-only group in comparison with 3.2% in the combination oral contraceptive (Yuzpe method) group.[17] The proportion of pregnancies prevented in this study was 85% with levonorgestrel and 57% with the combination oral contraceptive (Yuzpe) method in comparison with the expected number when no treatment was given. The effectiveness of emergency contraception might be summarized as follows: if 100 female adolescents have unprotected coitus in the middle of their menstrual cycles, estimates suggest that approximately 8 will become pregnant. Appropriate use of emergency contraception would reduce this number to approximately 2 pregnancies.[14]

Compared with 1.5 mg of levonorgestrel, ulipristal acetate has been shown to be equally efficacious when taken within 72 hours of unprotected intercourse. Glasier and colleagues[50] observed no statistically significant difference in pregnancy rates between women taking 30 mg of ulipristal (1.8%) or 1.5 mg of levonorgestrel (2.6%) within 72 hours of unprotected intercourse (odds ratio, 0.69%; 95% confidence interval, 0.35–1.31). This finding was consistent with a previous study.[51] Between 72 and 120 hours, the Glasier study showed some evidence that ulipristal may be more effective at preventing pregnancy.

## ADVERSE EFFECTS AND CONTRAINDICATIONS

### Levonorgestrel-Only Methods (Plan B, Plan B One Step, and Next Choice)

The only contraindication to use of levonorgestrel emergency contraception is known pregnancy because of lack of utility, not concern for teratogenicity or fetal loss. Young women with contraindications to estrogen may use levonorgestrel. The rate of nausea and vomiting with levonorgestrel emergency contraception is approximately half that with the combination oral contraceptive (Yuzpe) method, and routine use of antiemetics is not indicated.[17] Package labeling for the newest levonorgestrel emergency-contraception product, Plan B One Step, indicates that the most common adverse effect reported after use was heavier menstrual bleeding.[26]

Repeated use of levonorgestrel emergency contraception is associated with the same adverse effects as 1-time use. A recent Cochrane review of the subject found no serious adverse effects in trials of repeated use.[52]

### Ulipristal

The most common adverse effects reported by users of ulipristal include headache (18%), nausea (12%), and abdominal pain (12%).[28] As previously noted, animal studies suggest that fetal loss is a risk of use during the first trimester. No fetal malformations have been reported.[28] It is recommended to redose ulipristal if vomiting occurs within 3 hours of the initial dose.

### Yuzpe/Estrogen-Containing Methods

The most common adverse effects that occur during the first 24 to 48 hours of using estrogen-containing emergency-contraception methods are nausea (approximately 50%) and vomiting (approximately 20%), which seem unaffected by food intake.[53–55] Other adverse effects might include fatigue, breast tenderness, headache, abdominal pain, and dizziness.[14] The severity and incidence of nausea and vomiting can be decreased significantly by using an antiemetic 1 hour before an estrogen-containing regimen.[55] Antiemetics are ineffective if taken after nausea is present.[55] Effective oral antiemetics include meclizine, 25 to 50 mg, and metoclopramide, 10 mg by mouth, taken once before combination-hormone methods.[55,56] Patients with contraindications to estrogen use such as history of thromboembolism should not use the combination oral contraceptive (Yuzpe) method.

## OTHER CLINICAL CONSIDERATIONS

The discussion of emergency-contraception methods with patients must also include the fact that none of these methods will protect from STIs. Patients should be encouraged to contact their physician after use to schedule follow-up visits for STI testing or treatment, as indicated. In addition, these follow-up visits are an important time to discuss options for ongoing contraception, abstinence, and consensual intercourse. It should be emphasized to patients that emergency contraception is intended for emergency use and that routine use of

emergency contraception to prevent pregnancy is not as effective as the regular use of other forms of contraception. Although emergency contraception is exclusively for use by females, young men should be counseled on this method so that they may also suggest use to their female partners if needed.

## ADOLESCENTS AND EMERGENCY CONTRACEPTION: AWARENESS AND ACCESS

The regulatory changes and public discourse surrounding emergency contraception have increased the public's awareness of the methods; however, large numbers of teenagers still do not have much knowledge about correct use. In 2002, Aiken and colleagues[57] reassessed the awareness and knowledge of emergency contraception among 13- to 21-year-old females recruited from the same Pittsburgh clinic and drug treatment center from which they recruited participants for a 1996 study of emergency-contraception knowledge. Their study showed that, in 2002, 73% of teenagers were aware of emergency contraception, an increase from 44% in 1996. Although 95% of teenagers who were aware also knew where to get emergency contraception in 2002, up from 78% in 1996, only 52% were aware of the correct time frame for use (up from only 20% in 1996). Recent studies conducted in New York City and Hawaii found the percentage of teenagers aware of emergency contraception was closer to 50%.[58,59]

Data from the most recent 2006–2008 National Survey of Family Growth indicate that 14% of sexually experienced adolescent girls have ever used emergency contraception,[9] up from 8% in the 2002 survey. Reasons for use of emergency contraception by teenagers were examined by Alford et al[60] in a retrospective cohort study published in 2010. The most common reason for use was condom failure. Importantly, 13% of adolescents' use of emergency contraception during the study period was for nonconsensual penetration. A qualitative study conducted in Philadelphia aimed to explore teenagers' attitudes about the use of emergency contraception in more detail. Themes that emerged as barriers to emergency contraception use among the teenagers included worries about confidentiality, ability to get emergency contraception depending on age, worries about adverse effects, and lack of transportation to obtain the medication.[61] In a recent study of college-aged students, fewer than 16% knew that emergency contraception was available in their college health center.[62]

One important strategy to increase timely access to emergency contraception for adolescent girls is advanced prescribing. Advanced prescription for emergency contraception means providing a teenager with a supply or a prescription for emergency contraception before it is needed. Advanced prescribing facilitates access for teenagers in states that require prescriptions and also reduces the cost of obtaining emergency contraception for adolescents of all ages whose insurance provides coverage for emergency contraception with a prescription. In a 2010 review of 7 randomized trials of emergency contraception that included teenagers, it was shown that advanced prescription increased the use of emergency contraception and decreased time to use.[20] None of the studies showed an increase in sexual activity or decrease in ongoing contraceptive use in adolescents given advanced access to emergency contraception.

Despite evidence that improved access to emergency contraception (through advanced prescribing and allowing nonprescription access) increases the likelihood of use, no studies have demonstrated that improved access to emergency contraception reduces the pregnancy rate in a population.[63,64] There may be statistical reasons for this related to sample size of the studies, but it also may be that pregnancy rates remain unchanged overall because unprotected intercourse remains more frequent than emergency contraceptive use, despite increased access. The lack of demonstrated population level impact does not negate the potential for the method to reduce the risk of unintended pregnancy for an individual woman, however.

## ETHICAL DILEMMAS FOR PHYSICIANS AND PHARMACISTS

Despite multiple studies showing no increased risk behavior and evidence that hormonal emergency contraception will not disrupt an established pregnancy, public and medical discourse reflects that personal values of physicians and pharmacists continue to affect emergency-contraception access, particularly for adolescents.[65–70] Some physicians refuse to provide emergency contraception to teenagers, regardless of the circumstance, and others may provide emergency contraception only if nonconsensual penetration has occurred. Both of these choices by physicians have important adverse consequences for adolescents in their ability to access emergency contraception.

A study published in 2009 demonstrated that the decision to provide emergency contraception at a time of need but not in advance of need may be related to the physician's beliefs about whether it is okay for teenagers to have sex.[24] Often, physicians hold conflicting values when approaching reproductive health issues with teenagers. Physicians may object to

unprotected intercourse or intercourse outside of marriage, but they may also feel the need to prevent teen pregnancy. Pediatricians should strive to be aware of the ways in which the underlying beliefs they bring to their clinical practice affect the care that they provide.

The American Academy of Pediatrics has issued a policy statement on refusal to provide information or treatment on the basis of conscience.[71] According to the policy, pediatricians have a duty to inform their patients about relevant, legally available treatment options to which they object and have a moral obligation to refer patients to other physicians who will provide and educate about those services. Failure to inform/educate about availability and access to emergency-contraception services violates this duty to their adolescent and young adult patients.

## SUMMARY AND RECOMMENDATIONS

1. Pediatricians should be aware that sexual behavior is prevalent among teenagers and that as many as 10% of sexually active teenagers may be the victims of sexual assault.
2. Effective contraceptive use with dual methods (condoms in addition to hormonal contraception/intrauterine device) or abstinence are the best ways for teenagers to avoid pregnancy. Many teenagers are at high risk of contraceptive failure, however, and emergency contraception is an important backup method for all teenagers. Emergency contraception is most effective in decreasing risk of pregnancy when used as soon as possible, but it may be used 120 hours after unprotected or underprotected intercourse.
3. Indications for use of emergency contraception include sexual assault, -unprotected intercourse, condom breakage or slippage, and missed or late doses of hormonal contraceptives, including the oral contraceptive pill, contraceptive patch, contraceptive ring, and injectable contraception.
4. Pediatricians should provide levonorgestrel 1.5 mg (Plan B, Plan B One Step, or Next Choice) for teenagers in immediate need of emergency contraception and provide prescriptions/supply for teenagers to have on hand in case of future need (ie, advanced provision). No pregnancy test is required before the use of levonorgestrel.
5. The levonorgestrel method has an improved adverse effect profile and increased effectiveness compared with combined hormonal emergency-contraception methods. The rate of nausea and vomiting with levonorgestrel emergency contraception is approximately half that with the combination oral contraceptive (Yuzpe) method, and routine use of antiemetics is not indicated. Advanced provision increases the likelihood that teenagers will use emergency contraception when needed, reduces the time to use, and does not decrease condom or other contraceptive use. Females 17 years or older may obtain levonorgestrel without a prescription, but must show proof of age. Males may obtain levonorgestrel only if they are 18 years or older and can provide proof of age.
6. Other emergency-contraception methods include ulipristal (ella) and estrogen-containing (Yuzpe) emergency-contraception methods. Adverse effects of ulipristal include headache, nausea, and abdominal pain. Existing pregnancy must be excluded before prescribing ulipristal. The adverse effects of the estrogen-containing emergency contraception (Yuzpe) method include nausea, vomiting, and abdominal pain. Patients with contraindications to estrogen use, such as history of thromboembolism, should not use the combination oral contraceptive (Yuzpe) method.
7. All adolescents, males and females, and families of disabled adolescents should be counseled on emergency contraception as part of routine anticipatory guidance in the context of a discussion on sexual safety and family planning regardless of current intentions for sexual behavior. All contraceptive and STI counseling for adolescents should include education and counseling regarding the use and availability and advance prescription of emergency contraception wherever these visits occur, including emergency departments, clinics, and hospitals. Adolescents should be instructed to use emergency contraception as soon as possible after unprotected intercourse and to then schedule a follow-up appointment with their primary provider to address the need for STI testing and ongoing contraception.
8. At the policy level, pediatricians should advocate for increased nonprescription access to emergency contraception for teenagers regardless of age and for insurance coverage of emergency contraception to reduce cost barriers.

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