

# A<sup>Ph</sup>A Special Report

A Continuing Education Program for Pharmacists

# Emergency Contraception: The Pivotal Role of the Pharmacist



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## Advisory Board

### **Don Downing, RPh**

Clinical Associate Professor  
Department of Pharmacy  
University of Washington  
Seattle, Washington

### **Michelle Kasperowicz, RPh**

Pharmacist  
ShopRite Pharmacy  
Woodbridge, New Jersey

### **Emily L. Rowe, PharmD**

Clinical Pharmacist  
Children's National Medical Center  
Washington, DC

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*Michelle Kasperowicz, RPh*, declares no conflicts of interest or financial interests in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

*Emily L. Rowe, PharmD*, declares no conflicts of interest or financial interests in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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## Program Preview

Emergency contraception is one of the most important women's health issues today. Although millions of women have used it, millions more are not aware of its improved availability. Further, widespread confusion exists about emergency contraception among consumers and health care professionals alike.

Emergency contraception offers pharmacists a number of significant opportunities to meet the reproductive health needs of women. In the broader scope, pharmacists can perform a valuable community service by making emergency contraceptives available and educating the public about them. And on a person-to-person level, pharmacists can assist individual patients in determining whether emergency contraception is right for them and, if so, how to use it safely and effectively.

In order to take advantage of these opportunities, pharmacists must fully understand emergency contraception—what it is (and what it isn't), how it works, and which patients can benefit from it. Its availability is accompanied by some unique circumstances that the pharmacist must also fully understand: the product's dual status as an over-the-counter (OTC) and a prescription drug, the requirement to verify the age of those requesting it, and its behind-the-counter stipulation.

The OTC status of progestin-only emergency contraceptives has had an enormous impact on pharmacy practice, significantly increasing the need for pharmacists and their ancillary staff to understand the product and ensure that their patients are counseled. This is especially important because the pharmacist may be the only health care professional a woman consults about emergency contraception.

This Special Report presents the latest information on these topics and other related issues, to educate the pharmacist so that he or she is able to provide better patient care.

## Learning Objectives

After reading this monograph, the pharmacist will be able to:

1. Define emergency contraception and describe how it works.
2. Identify situations in which emergency contraception may be indicated.
3. Describe methods of emergency contraception currently available.
4. Discuss behind-the-counter and dual-status products.
5. Discuss the role of the pharmacist in dispensing emergency contraceptives and counseling patients on their proper use.

# Introduction

Nearly one out of every two pregnancies in the United States every year is unintended. Approximately half of the 3 million unintended pregnancies end in abortion.<sup>1,2</sup> The majority of women in their childbearing years (aged 15 to 44 years) use some form of contraception, but nearly half of all unintended pregnancies occur when these women experience contraceptive failure. Most of the remaining pregnancies occur in women not using a contraceptive method.<sup>3</sup> The scope of the problem can be seen from the data in Table 1.<sup>4</sup>

The Guttmacher Institute, a research group dedicated to advancing sexual and reproductive health, estimates that emergency contraception has the potential to cut the U.S. unintended pregnancy rate in half, resulting in approximately 600,000 fewer abortions per year.<sup>5</sup> Others project that correct use of emergency contraception could prevent 2 million unplanned pregnancies and 1 million abortions each year.<sup>6</sup>

Emergency contraception is defined as the use of a drug or device within 72 to 120 hours after unprotected intercourse for the purpose of preventing unintended pregnancy.<sup>7</sup> There are three methods for emergency contraception in use today<sup>7</sup>:

1. Use of a progestin-only hormonal medication containing a high dose of levonorgestrel.
2. Administration of special doses of combination hormonal oral contraceptives.
3. Insertion of a copper-releasing intrauterine device (IUD).

In this Special Report, we will focus on the pharmacologic methods of emergency contraception.

The use of oral contraceptives for emergency contraception dates back to 1974 when a Canadian physician, Albert Yuzpe, demonstrated that the use of large doses of oral contraceptives (combination estrogen and progestin) taken in two doses, 12 hours apart, within 72 hours after unprotected intercourse was a safe and effective method for preventing pregnancy.<sup>8</sup> In 1997, the U.S. Food and Drug Administration (FDA) declared the use of birth control pills using the Yuzpe regimen to be safe and effective; such off-label use of medications is legal and common in American medical practice.<sup>8,9</sup>

Products specifically indicated for emergency contraception were introduced in 1998 (combination oral contraceptives, brand name Preven) and in 1999 (levonorgestrel-only tablets, brand name Plan B).<sup>10</sup> Preven has since been withdrawn from the market.

Pharmacists have become a critical link between emergency contraception and the women who need it. Reducing unintended pregnancies is easier to achieve today than ever before, because of expanded availability of emergency contraceptives through community pharmacies. Most women can obtain progestin-only emergency contraceptives without a prescription; those under the

Table 1.

## Fast Facts About Unintended Pregnancy

- There are 6 million pregnancies per year in the United States.
  - 4 million live births.
  - 1.2 to 1.5 million abortions; remainder lost due to miscarriage, ectopic pregnancy, molar pregnancy, stillbirth.
- About 3 million pregnancies per year are unintended.
  - Nearly half occur when a contraceptive method fails.
  - Most of the remaining pregnancies occur among women who don't use contraception.
  - About 100,000 occur in girls younger than 18 years.
  - Up to half end in abortion.
- There are 60 million women in their childbearing years (ages 15 to 44 years).
  - 70% are sexually active.
  - 64% use some form of contraception.
- 1 in 20 American women has an unintended pregnancy each year.

Source: References 1, 3, 4, 5.

age of 18 years and low-income women still require a prescription, may have difficulty affording OTC products or may need a prescription in order to satisfy Medicaid requirements.

Although emergency contraception has become widely accepted, areas of confusion remain. First, its description as the “morning-after” pill is misleading. Emergency contraceptives do not need to be taken on the morning after unprotected intercourse—depending on the formulation, the dosage may be taken at any time of day up to 120 hours after the event.<sup>11,12</sup> In addition, emergency contraception is not one pill. In currently available regimens, the dosage ranges from two pills for progestin-only emergency contraceptives to 10 pills in some combination oral contraceptive regimens.

Second, confusion among consumers and health care providers about the differences between emergency contraception and medication abortion persists.<sup>5</sup> As can be seen in Table 2,<sup>1,5,7,12,13</sup> they are two distinct procedures: although both use oral medication, emergency contraception *prevents* pregnancy, while medication abortion *terminates* an existing pregnancy.<sup>13</sup> Emergency contraceptives are not teratogenic and cannot disrupt an established pregnancy (after implantation of a fertilized egg in the lining of the uterus).<sup>10</sup>

Table 2.

## Emergency Contraception vs Medication Abortion

Parameter	Emergency Contraception	Medication Abortion
Components	<ul style="list-style-type: none"> <li>Pills containing hormones               <ul style="list-style-type: none"> <li>– Progestin-only emergency contraceptive: 2 tablets, each containing 0.75 mg levonorgestrel.</li> <li>– Various oral contraceptives: 4 to 10 tablets, containing combination of progestin and estrogen, depending on brand.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>2 medications (abortifacients):               <ul style="list-style-type: none"> <li>– mifepristone (RU-486) or</li> <li>– methotrexate.</li> </ul> </li> <li>Either one taken in conjunction with misoprostol.</li> </ul>
Action	<ul style="list-style-type: none"> <li>Prevents pregnancy.</li> </ul>	<ul style="list-style-type: none"> <li>Terminates pregnancy.</li> </ul>
Mechanism of action	<ul style="list-style-type: none"> <li>Delays or inhibits ovulation, and/or inhibits fertilization by disrupting transport of sperm and/or egg; may also act by inhibiting implantation.</li> </ul>	<ul style="list-style-type: none"> <li>Mifepristone blocks the hormones necessary for maintaining a pregnancy.</li> <li>Methotrexate stops development of the pregnancy in the uterus.</li> <li>Misoprostol causes the uterus to contract and expel its contents.</li> </ul>
Process	<ul style="list-style-type: none"> <li>2 doses of the pills are taken either at one time (progestin-only regimen) or 12 hours apart.</li> <li>Must be initiated within 120 hours (5 days) of unprotected intercourse to be effective; the sooner treatment is initiated, the more effective it will be.</li> </ul>	<ul style="list-style-type: none"> <li>Pills are taken up to 49 days (methotrexate) or 56 days (mifepristone) after the first day of the last menstrual period.</li> <li>Bleeding and cramping begin soon after taking pills; more than half of women using this method abort within 4 to 5 hours after taking misoprostol.</li> <li>Bleeding may continue for 13 days; spotting may continue for a few weeks.</li> </ul>
How long does it take?	NA	<ul style="list-style-type: none"> <li>Mifepristone: 92% of abortions are completed in 1 week.</li> <li>Methotrexate: 75% of abortions are completed in 1 week; may take up to 4 weeks.</li> </ul>
Effectiveness	<ul style="list-style-type: none"> <li>Progestin-only emergency contraception is most effective.               <ul style="list-style-type: none"> <li>– Reduces risk of pregnancy by 95% when taken within 24 hours of unprotected sex; by 89% when taken within 72 hours.</li> </ul> </li> <li>Combination pills reduce risk of pregnancy by 75% when taken within 72 hours.</li> </ul>	<ul style="list-style-type: none"> <li>Complete abortion occurs in 92% to 96% of pregnancies after taking methotrexate; in 96% to 97% after taking mifepristone.</li> </ul>
Safety	<ul style="list-style-type: none"> <li>Safe for almost all women.</li> </ul>	<ul style="list-style-type: none"> <li>Safe for most women.</li> </ul>
Side effects	<ul style="list-style-type: none"> <li>Nausea and vomiting are most common; breast tenderness, fatigue, irregular bleeding, abdominal pain, headaches, and dizziness may occur.</li> <li>Side effects are much more common after taking combination pills than progestin-only pills.</li> </ul>	<ul style="list-style-type: none"> <li>Side effects are those seen with miscarriage: abdominal pain, bleeding, changes in body temperature, dizziness, fatigue, and gastrointestinal distress.</li> </ul>
Satisfaction	<ul style="list-style-type: none"> <li>More than 90% of users are satisfied; 97% would recommend it to friends and family; 92% would use it again.</li> </ul>	<ul style="list-style-type: none"> <li>Overwhelming majority of women were satisfied; 97% would recommend it to friends and family; 91% would do it again.</li> </ul>
Availability	<ul style="list-style-type: none"> <li>Progestin-only emergency contraceptives are available without a prescription for those 18 years and older behind the counter at pharmacies; women under 18 years require a prescription.               <ul style="list-style-type: none"> <li>– Pharmacists in 9 states can initiate the prescription under collaborative practice agreements or state protocols.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Must be done under the supervision of a clinician.</li> </ul>
Cost	<ul style="list-style-type: none"> <li>Varies, ranging from \$10 to \$50.</li> </ul>	<ul style="list-style-type: none"> <li>Ranges between \$350 and \$575 for 2 to 3 office visits, testing, and examinations.</li> </ul>

Source: References 1, 5, 7, 12, 13.

## They're Really Not "Morning-after" Pills

Confusion persists about emergency contraceptives. They are often called "morning-after" pills, but this is a misnomer, for several reasons:

- They do not need to be taken in the morning after unprotected intercourse.
- They may be taken sooner.
- They may be taken up to 120 hours (5 days) later—although they are most effective when taken in the first 24 hours.

Source: References 11 and 12.

## How Emergency Contraception Works

Although research has confirmed that certain doses of levonorgestrel or combination oral contraceptives as described by Yuzpe succeed in preventing pregnancy, the precise mechanism of action of emergency contraceptives remains uncertain. If unprotected intercourse occurs before ovulation, emergency contraceptives inhibit or delay the release of an egg from the ovary and may prevent the sperm and egg from uniting. If unprotected intercourse occurs post-ovulation, emergency contraception does not alter ovarian hormone levels, and it is unclear whether it has a contraceptive effect or not.<sup>1,10,12,14,15</sup>

## Indications for Emergency Contraception

Emergency contraception is indicated in women of reproductive age to prevent pregnancy following unprotected intercourse or contraceptive failure (known or suspected).<sup>16</sup> By preventing unintended pregnancy, it may reduce the demand for abortion.<sup>17</sup>

Some of the reasons that women give when requesting emergency contraceptives are listed in Table 3.<sup>17–19</sup> Failure to use contraception and malfunction of the contraceptive are the number-one and number-two most often cited reasons.<sup>1,10</sup>

Emergency contraceptives may also be used as back-up for other methods among women who experience frequent mishaps with use of their primary contraceptive method. Some women using oral contraceptives, the patch, or the ring often forget to resume their method following the "placebo week." Those who resume ongoing hormonal methods 1 to 2 days late have a heightened risk of ovulation and pregnancy if sexual intercourse occurs during this time.

Emergency contraceptives may also be used by those who are late getting their birth-control shots. In these cases, the patient should take the emergency contraceptives and then resume her ongoing hormonal method the following day, according to her provider's instructions.<sup>5</sup>

## Oral Agents for Emergency Contraception

Two types of oral contraceptive tablets are FDA approved for use as emergency contraception in the United States.<sup>7,8,20–22</sup>

- Progestin-only tablets: This is the only product specifically packaged for emergency contraceptive use and is supplied as two tablets, each containing 0.75 mg of levonorgestrel.
- Combination oral contraceptives: These contain a combination of progestin and estrogen. Although they are not indicated specifically for emergency contraception, they have been proven safe and effective for preventing pregnancy when taken in large doses in the few days after unprotected intercourse or contraceptive failure. Combination oral contraceptives may be an effective back-up method if progestin-only contraceptives are not readily available.

The progestin-only emergency contraceptive was approved by the FDA in 1999 as a prescription-only product. In 2006, FDA approved it as an OTC product available to anyone over the age of 18 years, including a woman's parents or boyfriend.<sup>23</sup> Women 17 years and younger continue to require a prescription.<sup>20</sup> Men under the age of 18 years cannot request a prescription.<sup>23</sup> FDA granted the manufacturer 3-year exclusivity, which will expire in August 2009.<sup>21</sup> Progestin-only emergency contraceptives are available in a single package of two tablets whether provided OTC or with a prescription. This product has largely replaced the use of combination oral contraceptives for emergency contraception because of its superior efficacy and reduced side effects.<sup>12</sup> Combination oral contraceptives remain available by prescription only.

## Dosing Strategies

Emergency contraceptives are, in general, taken in two doses. The first dose should be taken as soon as possible (but not later than 120 hours) after unprotected intercourse or failure of the contraceptive method used. The second dose should be taken 12 hours later; however, taking the second dose an hour or two earlier or later does not alter effectiveness. The regimen is effective as long as the second dose is taken within 24 hours after the first dose; this method may be preferred when patients don't want to get up in the middle of the night to take the second dose.<sup>11,24</sup>

Research has shown that both doses of progestin-only emergency contraceptives may be taken simultaneously without

Table 3.

## Reasons for Requesting Emergency Contraceptives

- No contraceptive method was used.
- The condom ruptured, slipped off, or was improperly applied.
- The woman forgot to take birth control pills or missed taking two consecutive pills.
- She forgot to insert her contraceptive ring or to apply the contraceptive patch.
- She is late for her contraceptive injection:
  - More than 3 days late for a combined estrogen plus progestin injection (e.g., medroxyprogesterone acetate and estradiol cypionate).
  - More than 2 weeks late for a progestin-only contraceptive injection (e.g., depot medroxyprogesterone acetate).
- Her diaphragm, cap, or shield slipped out of place.
- She miscalculated her “safe” days.
- Failed coitus interruptus.
- She was forced to have unprotected intercourse.

Source: References 17-19.

compromising efficacy. Studies have shown that, based on pharmacokinetic data and patient outcomes, a single dose of levonorgestrel 1.5 mg is as effective as—or slightly more effective than—the two-dose regimen described in the labeling.<sup>24</sup>

Simplified dosing may encourage adherence and optimize efficacy. A number of professional organizations, including the American College of Obstetricians and Gynecologists, Planned Parenthood, Family Health International, WHO, the International Consortium for Emergency Contraception, and the American Academy of Pediatrics, have officially endorsed the single-dose regimen.<sup>24</sup>

Recommended dosages for the oral contraceptive formulations used for emergency contraception in the United States today are listed in Table 4.

## Efficacy of Emergency Contraceptives

The effectiveness of emergency contraception is influenced by two time factors: the point in a woman’s menstrual cycle when she had unprotected intercourse, and the amount of time elapsed before she takes an emergency contraceptive. The earlier emergency contraceptives are taken after intercourse, the more effective they are.<sup>1,17</sup>

A study by WHO documented pregnancy rates of 0.5% to 1.5% when emergency contraceptives were taken in the first 12 to 24 hours, 2.6% at 48 hours, and 4.1% at 72 hours (based on combined efficacy associated with progestin-only and combination emergency contraceptives).<sup>1</sup> (See Figure 1.)

Research has shown that taking progestin-only emergency contraceptives within 72 hours of unprotected intercourse reduces the risk of pregnancy by 89%. When taken within 24 hours, this method of emergency contraception was found to reduce the risk by 95%. The Yuzpe regimen reduces the risk of pregnancy by roughly 75% if started within 72 hours of unprotected intercourse.<sup>9</sup>

Another WHO controlled trial showed that progestin-only emergency contraceptives were more effective than combination oral contraceptives when each was started within 72 hours: the overall pregnancy rate for the former was 1.1%, compared with 3.2% in those taking combination emergency contraceptives.<sup>25</sup> Thus, the risk of pregnancy was approximately one third less for those taking progestin-only emergency contraceptives compared with the combined method.<sup>10,25</sup> Combined data from two randomized trials that compared the two regimens showed that the chance of pregnancy among women who took the progestin-only regimen was about half that among those who received the combined regimen.<sup>12</sup> A recent Canadian study, using a revised method for estimating risk of pregnancy among women requesting medication for emergency contraception, calculated the overall risk of pregnancy to be 4.12%. That study included 11,795 women, 60% of whom used the progestin-only product.<sup>26</sup>

A woman’s most fertile period extends from 6 days preceding ovulation to the day after ovulation. There is lower efficacy for emergency contraceptives during this period than at other times in her monthly cycle.<sup>1</sup> In fact, the closer a woman is to ovulation at the time of unprotected intercourse, the less likely the method will be effective.<sup>17</sup>

Emergency contraception is not effective against subsequent acts of protected or unprotected intercourse during the period of

### How Is Pregnancy Risk Determined?

On average, about 8 of 100 women will become pregnant after having unprotected intercourse during the second or third week of their menstrual cycles.

- With emergency contraception using the Yuzpe method, only 2 of those 100 will become pregnant—a reduction of six pregnancies, or 75%.
- Using progestin-only emergency contraceptives, only one would become pregnant—a reduction of 89%.

Source: References 17 and 27.

Table 4.

## Oral Contraceptives for Emergency Contraception

Brand (Company)	Ingredient(s) per Tablet		Recommended Dosing <sup>a,b</sup> Pills per Dose
	Levonorgestrel	Ethinyl estradiol	
<b>Total dose: 2 tablets</b>			
Plan B (Duramed/Barr)	0.75 mg	none	1 white tablet, taken twice. Both doses may be taken simultaneously.
<b>Total dose: 4 tablets</b>			
Ogestrel (Watson)	0.25 mg	0.50 µg	2 white tablets, taken twice.
Ovral (Wyeth-Ayerst)	0.25 mg	0.50 µg	2 white tablets, taken twice.
<b>Total dose: 8 tablets</b>			
Cryselle (Duramed/Barr)	0.30 mg	0.15 µg	4 white tablets, taken twice.
Enpresse (Duramed/Barr)	0.30 mg	0.15 µg	4 orange tablets, taken twice.
Jolessa (Duramed/Barr)	0.30 mg	0.15 µg	4 pink tablets, taken twice.
Levlen (Berlex)	0.30 mg	0.15 µg	4 light orange tablets, taken twice.
Levora (Watson)	0.30 mg	0.15 µg	4 pink tablets, taken twice.
Lo/Ovral (Wyeth Pharmaceuticals)	0.30 mg	0.15 µg	4 white tablets, taken twice.
Low-Ogestrel (Watson)	0.30 mg	0.15 µg	4 white tablets, taken twice.
Nordette (Wyeth Pharmaceuticals)	0.30 mg	0.15 µg	4 light orange tablets, taken twice.
Portia (Duramed/Barr)	0.30 mg	0.15 µg	4 pink tablets, taken twice.
Quasense (Watson)	0.30 mg	0.15 µg	4 white tablets, taken twice.
Seasonale (Duramed/Barr)	0.30 mg	0.15 µg	4 pink tablets, taken twice.
Seasonique (Duramed/Barr)	0.30 mg	0.15 µg	4 light blue-green tablets, taken twice.
Tri-Levlen (Berlex)	0.30 mg	0.15 µg	4 yellow tablets, taken twice.
Triphasil (no longer marketed)	0.30 mg	0.15 µg	4 yellow tablets, taken twice.
Trivora (Watson)	0.30 mg	0.15 µg	4 pink tablets, taken twice.
<b>Total dose: 10 tablets</b>			
Alesse (Wyeth Pharmaceuticals) (no longer marketed)	0.10 mg	0.20 µg	5 pink tablets, taken twice.
Aviane (Duramed/Barr)	0.10 mg	0.20 µg	5 orange tablets, taken twice.
Lessina (Duramed/Barr)	0.10 mg	0.20 µg	5 pink tablets, taken twice.
Levliite (Berlex)	0.10 mg	0.20 µg	5 pink tablets, taken twice.
Lutera (Watson)	0.10 mg	0.20 µg	5 white tablets, taken twice.

<sup>a</sup>Published dosing regimens specify taking the first dose within 72 hours and the second dose 12 hours later.

<sup>b</sup>Emergency contraceptive pills are most effective when taken early—within the first 24 hours. However, they may be initiated up to 120 hours after unprotected intercourse or condom failure.

NOTE: In dispenser-type packages of 28 pills, only the first 21 pills can be used.

Source: Reference 11.

treatment.<sup>28</sup> It may also be less effective in women taking certain drugs: phenytoin, carbamazepine, barbiturates, and rifampin.<sup>28</sup>

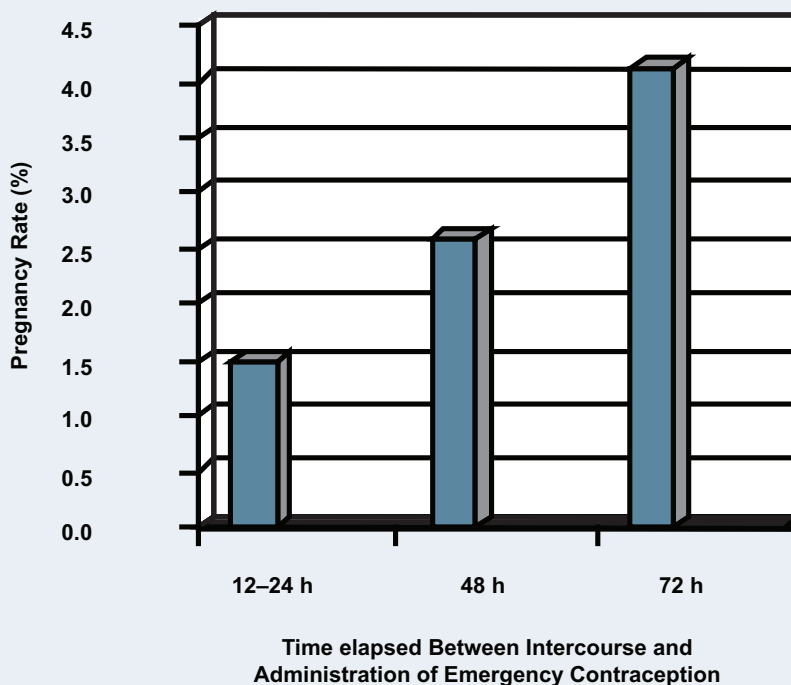
It is important to note that emergency contraception is neither as effective as correct and consistent use of standard contraceptive methods such as oral contraceptives, IUDs, implants, injections, patches, or rings, nor does it protect against sexually transmitted diseases.<sup>17</sup>

## Safety of Emergency Contraceptives

Millions of women have used emergency contraceptives safely and effectively. Almost every woman who needs emergency contraceptives can safely use them, even those with contraindications to

Figure 1.

## Pregnancy Rate Increases With Time



Source: Reference 1.

the routine use of oral hormonal contraceptives. In fact, research has shown that pregnancy poses a greater threat to women with medical problems such as thromboembolic and liver disease than does a 1-day dose of estrogen and/or progestin.<sup>5</sup> Emergency contraceptives also have been found to be safe and well tolerated by teens between the ages of 13 and 16 years.<sup>9</sup> Postmarketing surveillance since 1999 has shown no increase in the risk of ectopic pregnancies and no reports of overdose, overuse, or abuse.<sup>28</sup>

It has been suggested that the progestin-only regimen may be a better choice for women with a personal or family history of thrombosis.<sup>29</sup> Because this method does not contain estrogen, it has not been linked to cardiovascular risks such as deep vein thrombosis, myocardial infarction, or stroke.<sup>28</sup>

There are no evidence-based contraindications to emergency contraceptives except pregnancy.<sup>7,29</sup> The only women who should not use emergency contraceptives are those who are already pregnant—not because the treatment is unsafe, but because it will have no effect on the pregnancy.<sup>9</sup>

The most common side effects among women in the clinical trial for progestin-only emergency contraceptives are listed in Table 5.

There are significantly fewer side effects with progestin-only emergency contraceptives than with combination tablets. Combination-hormone emergency contraceptives can cause nausea in up to 50% of women and vomiting in up to 25%.<sup>9,11,16</sup> (See Figure 2.)

## Access to Emergency Contraceptives

One of the concerns expressed about making emergency contraceptives available OTC was that easy access would encourage women, particularly adolescents, to increase risky sexual behavior and reduce their routine use of regular methods of contraception. This fear has proven to be unfounded, since numerous studies have shown that improved access to emergency contraceptives does not increase risky sexual behavior in adolescents or adults.<sup>23,30</sup> In a study conducted in San Francisco, teens aged 15 to 19 years who had either pharmacy access to or advance provision of emergency contraceptives did not exhibit an increase in their rates of unprotected intercourse, sexually transmitted diseases, or pregnancy.<sup>31</sup>

Table 5.

## Most Common Side Effects in Progestin-Only Emergency Contraceptives Clinical Trial

- Nausea (23.1%)
- Abdominal pain (17.6%)
- Fatigue (16.9%)
- Headache (16.8%)
- Heavier menstrual bleeding (13.8%)
- Lighter menstrual bleeding (12.5%)
- Dizziness (11.2%)
- Breast tenderness (10.7%)
- Vomiting (5.6%)
- Diarrhea (5%)

Source: Reference 16.

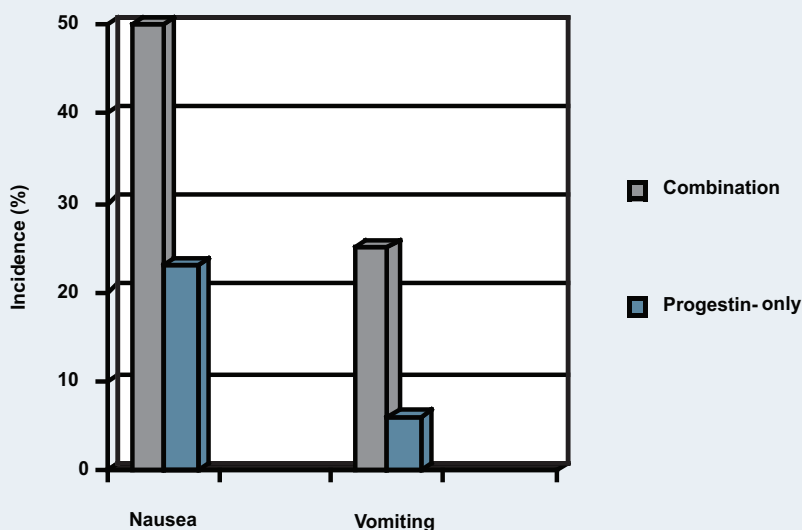
Timely access to emergency contraception is essential. Access has improved considerably since FDA approved OTC status for progestin-only emergency contraceptives in 2006 for anyone aged 18 years and older.

The need for emergency contraception most often arises suddenly or unexpectedly (i.e., following contraceptive failure or unprotected intercourse). Before the change in prescription status for emergency contraceptives, it was more difficult for patients to obtain emergency contraception. If such an episode occurred on a Friday night, a woman usually had to wait until Monday morning to call her health care provider and was not always able to get an appointment quickly. Emergency contraceptives are most effective when taken within 24 hours (by Saturday night, in this example) and should be taken within 72 hours (Monday evening, in this case). Although studies have shown that there is some degree of efficacy up to 120 hours later, the method's effectiveness wanes over time.<sup>1</sup>

Now, however, those who are 18 years or older may immediately obtain progestin-only emergency contraceptives at pharmacies nationwide. Pharmacies are preferred sources for emergency con-

Figure 2.

## Incidence of Common Side Effects



Source: References 9, 11, 16.

trapection because of their convenient locations and extended business hours.<sup>6</sup> The FDA specified that emergency contraceptives may not be sold in convenience stores or other retail outlets that do not provide pharmacy services.<sup>32</sup>

Emergency contraceptives may be obtained for subsequent use in the absence of an immediate need, a practice that is called advance provision. In addition to empowering women to have more control of their reproductive health, advance provision enables them to use emergency contraceptives more rapidly after unprotected intercourse, which increases effectiveness.<sup>33,34</sup>

FDA's decision to create dual-label status for progestin-only emergency contraceptives set a new precedent for providing a pharmaceutical product. Although this product is OTC for individuals 18 years and older, it must be kept behind the counter, where individuals need to request it and provide proof of age. The behind-the-counter/OTC status for emergency contraceptives accomplishes more than just satisfying the legal proof-of-age requirement—it also ensures that some level of professional consultation is available.<sup>35</sup>

Only the federal government can change a product's status from prescription-only to OTC, but states decide who can prescribe. Individual states have taken different paths to expand access to emergency contraception. Some require that emergency rooms provide information and/or dispense emergency contraceptives to victims of sexual assault. Others have drafted provisions for pharmacists to prescribe and dispense emergency contraceptives via collaborative practice agreements or a state-approved protocol. Nine states currently have such arrangements (see sidebar), and legislation to authorize pharmacists to prescribe emergency contraceptives is being considered in a number of other states, including Illinois, New Jersey, and New York (as of the summer of 2007).<sup>23</sup> On the other hand, some states have adopted restrictions on emergency contraception, such as excluding emergency contraceptives from contraceptive-coverage mandates.<sup>36</sup>

### What Does Your State Do?

You can find information about emergency contraception pharmacy-access programs, including emergency-contraception protocols, informed consent, encounter forms, and other relevant information for the following states at the Pharmacy Access Partnership Web site, <http://www.go2ec.org>.

Alaska	California
Hawaii	Maine
Massachusetts	New Hampshire
New Mexico	Vermont
Washington	

For information on emergency-contraception access and the status of collaborative protocols in your state, contact the state board of pharmacy or state pharmacists association.

## Special Considerations for Other Patient Populations

Access to emergency contraception remains limited for some patient populations such as women under the age of 18 years, women with low income, and women without proper identification, including undocumented residents.<sup>5, 23,37</sup> Most Medicaid beneficiaries and others seeking insurance coverage for emergency contraceptives still require a prescription. At an average retail price of about \$40, the cost of emergency contraceptives is too high for many, including college students.<sup>37</sup>

The American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Society for Adolescent Medicine have all supported the availability and use of emergency contraceptives in teens.<sup>5</sup> Studies show that adolescents are capable of using emergency contraceptives correctly and safely, and that access to emergency contraception is not associated with increased rates of unprotected intercourse, decreased use of condoms, or higher rates of pregnancy or sexually transmitted infections.<sup>5,39</sup> In one study of increased access to emergency contraception among adolescents and young adults, those younger than 16 years behaved no differently than older age groups with regard to unprotected intercourse or condom use, and were at no greater risk for sexually transmitted diseases, pregnancy, or unwanted sexual activity.<sup>31</sup>

Pharmacists can help these women obtain emergency contraceptives when needed by taking part in collaborative practice agreements or state protocols if available, or by offering a list of local physicians and clinics that provide prescriptions for emergency contraception.

## Awareness of Emergency Contraception

Availability is only half the equation for successful emergency contraception, however. Access depends in large measure on awareness of emergency contraception and its ready availability in pharmacies. Hence, there are numerous nationwide and state programs under way to increase awareness of emergency contraception.

- Emergency contraception Web sites for consumers and health care professionals have proliferated (See Resources box on page 13 for a list).
- The American College of Obstetricians and Gynecologists has instituted an “Ask Me” campaign, encouraging their members to place posters in their offices and wear “Ask Me” buttons that will provoke questions and initiate discussions about emergency contraception with their patients.<sup>40,41</sup>

- The American Medical Association (AMA) recently voted to adopt a new policy asking pharmacists to post signs or use their Web sites to let patients know whether they stock and dispense emergency contraceptives and whether a prescription is required. If a pharmacy does not stock emergency contraceptives, AMA requests that they use these channels to advise patrons where they can go to obtain emergency contraceptives.<sup>42</sup>
- Women's health advocacy groups are conducting awareness campaigns using local and wider media channels. Two examples are "It's Not Too Late" from the Office of Population Research at Princeton University and the Association of Reproductive Health Professionals, and "Back Up Your Birth Control with EC" from the Institute for Reproductive Health Access.

Other programs have been designed to enable women to obtain emergency contraceptives from the pharmacist in a discreet confidential manner. One such program, "Got Plan B?", was developed by the Pharmacy Access Partnership and the Pacific Institute for Women's Health when research revealed that young women would be more likely to seek emergency contraceptives in the pharmacy if there were a way to have a private conversation away from others at the pharmacy window. The program's wallet-sized Client Confidentiality Cards can be presented at the pharmacy counter to request emergency contraceptives nonverbally. Distribution of the cards began in California in July 2007, with plans to expand nationally in the future.<sup>43</sup>

In a California study of trends in emergency contraception awareness, researchers found that overall awareness had increased from 40% in 1999 to 57% in 2004. However, they found low levels of awareness among foreign-born Hispanic women, women whose income falls below the poverty level, and those who did not complete high school. These findings suggest that educational efforts should be tailored to women who may be outside the reach of traditional media.<sup>44</sup>

## The Pharmacist's Role in Emergency Contraception

The change in the status of emergency contraception represents an unprecedented opportunity for pharmacists to help improve access to emergency contraception, opening new pathways for professional collaboration and patient interaction. A focus on emergency contraception can propel pharmacists closer to the clinical scope of services and professional development to which many aspire.<sup>45</sup> In a 2002 survey of pharmacists who provided emergency contraception services, the vast majority (91%) said they did so primarily because it is an important community

service. More than half (57%) recognized it as an opportunity for professional development.<sup>45</sup>

The new and unique status of progestin-only emergency contraceptives makes pharmacists the primary source of this important component of women's health care. Pharmacists are the principal source of emergency contraceptives for all individuals aged 18 years and older and a primary conduit for those under the age of 18 years. The pharmacist's responsibilities encompass a wide range of activities, including knowing and complying with legal requirements. Pharmacy emergency contraception services can also help improve the effectiveness of emergency contraceptives by reducing the time interval between unprotected intercourse and initiation of treatment.<sup>44</sup>

It will be helpful for pharmacists to be able to identify patients at high risk for unintended pregnancy who are therefore good candidates for emergency contraception. The unintended pregnancy rate among women ages 15 to 44 years was 51 per 1000 (i.e., about 5%) in 2001, the most recent year for which data are available.<sup>4</sup> Research has defined high-risk groups with above-average rates of unintended birth and abortion as follows:

- Women 18 to 24 years of age
- Cohabiting (unmarried) women
- Minority women
- Those living below the poverty line
- Those without a high school diploma

**Marital status.** The rates of unintended pregnancy and abortion are higher among unmarried women and are particularly high among cohabiting women. Among married women, more than one quarter of pregnancies are unintended.<sup>4</sup>

**Income level.** The unintended pregnancy rate ranged from 112 per 1000 among women below the poverty line to 29 per 1000 for those whose income was at least twice the poverty level. Abortions increased while the rate of unintended births declined sharply with higher income.<sup>4</sup>

### Add Your Pharmacy

To be added to the directory on the [www.not-2-late.com](http://www.not-2-late.com) Web site, operated by the Office of Population Research at Princeton University and the Association of Reproductive Health Professionals, pharmacists who stock and dispense emergency contraceptives can obtain the registration form at <http://ec.princeton.edu/providerform.pdf>.

The completed and signed form may be mailed or faxed to:  
 Emergency Contraception Hotline  
 Office of Population Research  
 Wallace Hall  
 Princeton University  
 Princeton, NJ 08544  
 Fax: (609) 258-1039

**Education.** Among women aged 20 years and older, those without a high school diploma had an unintended pregnancy rate about three times that of college graduates.<sup>4</sup>

**Race and ethnicity.** The rates of unintended pregnancy vary dramatically by race, with the highest rates among black and Hispanic women.<sup>4</sup>

## Legal Requirements

The OTC status of progestin-only emergency contraceptives is accompanied by legal requirements. Primary among these is the requirement to confirm that individuals requesting emergency contraceptives without a prescription be at least 18 years old. The types of identification that may be used to check age are listed in Table 6.

To enforce this provision, the FDA stipulated in its approval of this product that the manufacturer must conduct surveys to determine that the requirement for a prescription for those under the age of 18 years is being adhered to at the point of purchase. The company must also conduct a point-of-purchase monitoring program, including the use of anonymous shoppers, to document and analyze that the prescription age requirement is being followed in pharmacies.<sup>32,46</sup>

Table 6.

### Acceptable Forms of Proof of Age for Obtaining Emergency Contraceptives Without a Prescription

- U.S. or Canadian driver's license<sup>a</sup>
- U.S. passport (current or expired)
- Alien Registration Receipt Card/Permanent Resident Card (green card)
- Unexpired foreign passport that contains a temporary I-551 stamp
- School ID card with photo
- Voter's registration card
- U.S. military card
- ID card issued by federal, state, or local government agencies or entities<sup>a</sup>
- Military dependent's ID card
- Native American tribal identification documents
- U.S. Coast Guard Merchant Mariner Card

<sup>a</sup>Driver's licenses or ID cards issued by federal, state, or local government agencies that do not have a photograph are acceptable if they include identifying information such as name, date of birth, sex, height, color of eyes, and address.

Source: Reference 11.

State laws and collaborative practice agreements vary, and pharmacists must be aware of the standards, education/training provisions, and documentation requirements in their state. Pharmacists should also be aware of their state's guidelines and their employer's policies regarding conscience clauses, i.e., their responsibilities regarding stocking, prescribing or dispensing emergency contraceptives when they have a moral or religious objection to doing so.

## Dispensing Emergency Contraceptives

Although practices vary from pharmacy to pharmacy, and from state to state, there are certain standard procedures involved in a pharmacist's encounter with an individual seeking emergency contraceptives. The collaborative practice agreement in the state of Washington provides insight into the emergency contraception process. It is outlined in Table 7.<sup>47</sup>

Pharmacists should be aware that some patients may feel stressed or embarrassed when inquiring about emergency contraceptives. Counseling should take place in a private setting, and the pharmacist should not be judgmental or disapproving.<sup>19</sup> The encounter may be divided into several steps: screening, educating the patient about emergency contraceptives and their use, and counseling on contraception and related issues.

**Screening.** First, the pharmacist (or pharmacy technician) must verify that the patient is 18 years or older in order to receive emergency contraceptives without a prescription.

The pharmacist should then establish that a woman requesting emergency contraception is not pregnant, because in such cases, emergency contraceptives will have no effect. This can be done by inquiring about the date of the last menstrual period and the symptoms of early pregnancy (such as nausea, fatigue, sore or enlarged breasts, headaches, and frequent urination). If the patient has missed a period or has symptoms consistent with pregnancy, she should have a pregnancy test.<sup>19</sup>

**Educating the Patient About Emergency Contraceptives.** The pharmacist should discuss the role of emergency contraception in preventing pregnancy and ask when the incident of unprotected intercourse occurred. Advise patients that emergency contraceptives are more effective the sooner they are taken. If more than 72 hours but less than 120 hours have elapsed since the unprotected intercourse, advise the patient that emergency contraception may be initiated but will likely be less effective than if it had been taken sooner. If more than 120 hours have elapsed, advise the patient to see a physician and provide names and contact information if she does not have a regular health care provider.

If the decision to dispense emergency contraceptives is made, then the pharmacist can explain in greater detail what the patient can expect.

Table 7.

## Typical Components of Emergency Contraception Services

Elements from the Washington state program offer a framework that has been successful for more than 10 years in that state. Its stipulations include:

- Pharmacists must receive education/training in emergency contraception.
- After addressing the age requirement, the pharmacist determines the patient's eligibility—i.e., that the patient is not pregnant and has had unprotected intercourse within the past 72 hours.
- If the patient is a candidate for emergency contraceptives, the pharmacist and patient review and discuss emergency contraception—what it does, its limitations, potential adverse effects, and the importance of adherence to treatment.
- The patient reviews and signs a standard consent form.
- The pharmacist determines whether the patient should be referred immediately to other health care professionals for ongoing contraception (e.g., prescription for oral contraceptives or a diaphragm), or evaluated and treated for sexually transmitted diseases.
- Patients without a primary care physician are given names, phone numbers, and/or business cards of local health care providers or clinics where they can be seen.
- If the pharmacist suspects domestic violence or sexual abuse/rape, the patient may be referred to counseling resources or the state's Child Protective Services.

Source: Reference 47.

**Administration.** Advise patients to take the first dose as soon as possible and to take the second dose 12 hours later. Alternatively, research has shown that taking both of the progestin-only tablets at the same time does not affect efficacy and may increase compliance.<sup>9,24</sup> Patients should also be told not to take additional pills. Doing so will not improve their effectiveness and may increase side effects, particularly nausea.<sup>11</sup>

**Side Effects.** It is helpful to tell patients what side effects they might experience. These can include nausea, abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting, and diarrhea. Side effects are usually self-limiting, resolving within 24 hours.<sup>7,16</sup> Menstrual bleeding may also be heavier or lighter after using emergency contraception. Nausea and vomiting are more likely to occur with combination oral contraceptives than with progestin-only emergency contraceptives.<sup>11,48</sup>

The pharmacist may recommend taking an anti-nausea medicine such as OTC meclizine (25 to 50 mg) 1 hour before taking the emergency contraceptives, particularly if the Yuzpe

regimen using combination oral contraceptives is used.<sup>10,11</sup> Antiemetics are not usually recommended with the progestin-only regimen due to the low incidence of nausea and vomiting associated with that product.<sup>49</sup> If a patient vomits within 1 to 2 hours of taking the pill(s), she should repeat the dose.<sup>1,49</sup> She can return to the pharmacy to obtain additional pills if necessary. If vomiting occurs after 2 hours, there is no need to repeat the dose.<sup>1</sup>

In the event of severe nausea and vomiting, vaginal administration is an option, i.e., inserting the pill high into the vagina and holding it in place with a tampon. Research has shown that plasma levels sufficient to suppress ovulation can be achieved by this route.<sup>50,51</sup>

Patients who experience other symptoms such as the following should contact their health care provider right away:<sup>11</sup>

- Severe pain in the leg (calf or thigh)
- Severe abdominal pain
- Chest pain, cough, or shortness of breath
- Severe headache, dizziness, weakness, numbness
- Blurred vision, loss of vision, difficulty speaking
- Jaundice

**Resumption of Menstrual Periods.** For the majority of women taking progestin-only emergency contraceptives, the next period starts at about its regular time, although it might come a few days early or a few days late. A WHO study of women who used emergency contraceptives found:<sup>5,25</sup>

- Menses returned within 3 days of the anticipated date in 61% of women.
- The next period was delayed 4 to 7 days in 15% and more than 7 days in 13%.
- The next period came early in 11%.

Another study determined that the timing of the return of menses was related to the date of emergency contraceptive use within the patient's cycle: Those who took emergency contraceptives early in their cycle were most likely to get their next period earlier; those who took emergency contraceptives later in their cycle were more likely to have an on-time return of menses, although one third of these had an early period.<sup>5</sup> In a French study, 14.7% of women who received progestin-only emergency contraceptives experienced statistically significant changes in their menstrual cycle length, duration of their period, and the appearance of their menstrual discharge compared with baseline. The majority of the changes disappeared in the following cycle.<sup>22</sup> Menstrual bleeding may be heavier or lighter after using emergency contraception.<sup>16</sup>

Women who do not menstruate as expected should consider getting a pregnancy test.<sup>11</sup>

### Counseling on Contraception and Related Issues.

Patients requesting emergency contraception should be reminded

that it does not prevent HIV or other sexually transmitted infections.<sup>16,17</sup>

Patients should be warned that emergency contraceptives will not continue to prevent pregnancy during the remainder of their current cycle; other methods of birth control should be used.<sup>27</sup> Also, research has shown that women who had protected or unprotected intercourse again within a few days of emergency contraceptive use were found to have higher pregnancy rates than those who did not.<sup>24,25,28</sup>

Patients should be advised to start using a regular method of birth control, which is both more effective and less expensive than repeated use of emergency contraceptives.<sup>11,29</sup> Barrier methods or spermicide can be used immediately. A woman who is using oral contraceptives can start a new pack after her next period begins or can resume taking one pill a day of her regular oral contraceptive on the day after completing the emergency contraception regimen.<sup>1</sup> If a woman experiences frequent errors with her current contraceptive method, the pharmacist may suggest alternatives.

## Additional Considerations for Pharmacists

Many pharmacists offer emergency contraception to appropriate patients (such as condom users, parenting teens, and those taking oral contraceptives) in advance of need. Studies have shown that women with advance provision were more likely to use emergency contraceptives and to do so promptly—when it is most effective.<sup>33,34</sup>

Pharmacist assessment, consultation, and dispensing generally takes 10 to 15 minutes.<sup>35</sup> Policies about paying pharmacists for this type of service vary among states and insurance companies. Pharmacists should determine the procedures in their practice and undertake documentation as needed.

As emergency contraception has evolved, pharmacists in many states have been actively engaged in making it available to more women. This has been achieved through the development of collaborative practice agreements permitting pharmacists to prescribe and dispense emergency contraception.<sup>45</sup> Experts in pharmacy provision of emergency contraception urge all pharmacists to join their colleagues in providing this important component of women's health care. Their suggestions are listed in Table 8.

## Summary

The emergency contraception environment has changed considerably since the 2006 FDA approval of OTC status for progestin-only emergency contraceptives. This major shift in access brings with it new opportunities and responsibilities for pharmacists.

Table 8.

### Action Items for Pharmacists

- Stock and dispense emergency contraceptives.
- Make sure all of your pharmacy's employees, particularly those who answer the telephones, know that you provide emergency contraceptives.
- Routinely discuss emergency contraception with appropriate customers (e.g., new users of oral contraceptives, condom users).
- Provide emergency contraceptives in advance to patients over the age of 18 years.
- Determine your state's requirements for prescribing emergency contraceptives to patients 17 years of age or younger.
  - In states with collaborative practice agreements, prescribe emergency contraceptives for women younger than 18 years.
  - In other states, suggest that patients younger than 18 years obtain a prescription from their health care provider for use if emergency contraceptives are needed.
- Discuss antinausea medications with emergency contraception patients.
- Advertise the availability of emergency contraceptives in your pharmacy.
- List your pharmacy in directories of pharmacies carrying emergency contraceptives.
- Have an area available where you can discuss emergency contraception with patients confidentially.

Source: Reference 12.

The progestin-only emergency contraceptive is unique in that it is the only product that has received FDA approval as both a prescription and OTC product depending on the user's age. Because it is prescription-only for patients younger than 18 years, the package must be kept behind the pharmacy counter; it may be in full view but not where a customer can pick it up. It must be dispensed by a licensed pharmacist who has been trained in emergency contraception and its appropriate use. It cannot be dispensed without proof of age unless the patient has a prescription.

Pharmacists are in a unique position to assist patients in need of emergency contraception—primarily those who had unprotected intercourse or whose contraceptive method failed. As more women become aware of the improved access to emergency contraceptives, pharmacists will face more questions and more occasions for counseling. They are in a position to offer support on many levels, from counseling individual patients, to helping to inform the community, to becoming an advocate for improved access for low-income women and those under the age of 18 years at the state level.

## Resources

American College of Obstetricians and Gynecologists  
[www.acog.org](http://www.acog.org)

Association of Reproductive Health Professionals  
[www.arhp.org](http://www.arhp.org)

Center for Reproductive Rights  
[www.reproductiverights.org](http://www.reproductiverights.org)

Emergency Contraception Web site operated by Princeton University's Office of Population Research and the Association of Reproductive Health Professionals  
[www.NOT-2-LATE.com](http://www.NOT-2-LATE.com)

Institute for Reproductive Health Access  
[www.backupyourbirthcontrol.org](http://www.backupyourbirthcontrol.org)

National Center to Prevent Teen Pregnancy  
[www.teenpregnancy.org](http://www.teenpregnancy.org)

National Family Planning and Reproductive Health Association  
[www.nfprha.org](http://www.nfprha.org)

Pharmacy Access Partnership  
<http://pharmacyaccess.org>  
[www.go2ec.org](http://www.go2ec.org)

Plan B information page at U.S. Food and Drug Administration  
[www.fda.gov/cder/drug/infopage/planB/default.htm](http://www.fda.gov/cder/drug/infopage/planB/default.htm)

Plan B Web site, Duramed Pharmaceuticals, Inc  
[www.go2planb.com](http://www.go2planb.com)

Planned Parenthood Federation of America  
[www.plannedparenthood.org](http://www.plannedparenthood.org)

Princeton University's Office of Population Research  
<http://ec.princeton.edu>

Program for Appropriate Technology in Health (PATH)  
[www.path.org](http://www.path.org)

## The Washington State Experience With Emergency Contraception

Washington state pioneered the distribution of emergency contraceptives through pharmacies. In 1997, the Washington State Pharmacists Association launched a 2-year pilot project to determine the feasibility of emergency contraception access directly from pharmacies. After the first year of the program, the state Department of Health reported that the teen pregnancy rate had declined to its lowest level in 20 years, and the state's abortion rate had dropped more steeply than at any time in the past decade.

The project succeeded in improving access to emergency contraception and has become a model for pharmacy emergency contraception services in other states and countries. The state reimburses pharmacies for providing the pills and related services—screening, counseling, and referral—to Medicaid clients.

A critical component of Washington's program has been the collaborative drug therapy agreements under which physicians delegate authority to pharmacists trained in emergency contraception service provision, allowing pharmacists to prescribe a particular therapy according to a specific protocol. Such agreements have become the standard of pharmacy practice in Washington. While the legal framework permitting pharmacists to initiate emergency contraception is now only essential for those under the age of 18 years, the need for pharmacist education and counseling has increased as awareness of and demand for emergency contraception have grown.

The project also confirmed the value of pharmacists in improving access: More than 40% of women obtained emergency contraceptives from pharmacies during evenings, weekends, or holidays, highlighting the unique service that pharmacists can provide.

The project's resounding success led to the integration of pharmacy emergency contraception services into the state's health care and social service systems. This was made possible through a myriad of public agencies, private initiatives, grass-roots initiatives, and community networks of organizations receiving state funding for social and health services (such as migrant worker clinics, teenage outreach programs, plus independently funded groups).

Beyond dispensing emergency contraceptives, the Washington state programs have had wider consequences for reproductive health as well. Over a 12-month period, 76% of women who came to Washington state clinics for emergency contraception—who were not using a regular contraceptive method—subsequently began routine use of a contraceptive method.

The Washington State Pharmacists Association has cited the following lessons learned from their emergency contraception programs:

- Key groups—including pharmacy, medicine, and public health communities—in the state must be highly motivated to expand emergency contraception access through pharmacies; collaboration and substantial support of these key groups are essential to success.
- Initial intensive campaigns to raise awareness should be followed by subsequent sustainable, localized, and low-level marketing efforts, possibly pharmacy-based.
- After an initial intensive media campaign, word of mouth appears to grow and contributes to expanding awareness.
- Education of pharmacists is critical. Some pharmacists who were initially reluctant to provide emergency contraceptive services changed their minds after attending a training program. They indicated that they had misunderstood the mechanisms of emergency contraception.
- Fear of backlash is more inhibiting than actual negative reaction in the community. No boycotts occurred in Washington state; in fact, a number of pharmacists were told by new customers that they had gained their business because they offered this new service.

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*Source: References 38 and 47.*

## A Guide to Providing Emergency Contraception—What Would You Do?

Here are two scenarios from a typical encounter in the pharmacy. A teen-aged girl approaches your pharmacy technician and nervously asks how she can get the “morning-after” pill.

- 1. In one store, the pharmacy technician cheerfully tells her that the pharmacy dispenses progestin-only emergency contraceptives to anyone 18 years of age or older and asks to see her driver’s license. He verifies that she is at least 18 years old and dispenses emergency contraceptives.**
- 2. In another store, the pharmacy technician replies that the pharmacy can help her and asks to see her driver’s license or other government-issued identification card. He escorts her to a private area of the pharmacy and introduces her to the pharmacist who has been trained to provide emergency contraception services.**

### Who did the right thing?

In the first case, the pharmacy technician verified her eligibility. With the surveillance provision mandated by the FDA, pharmacists and their employees would be wise to treat every customer as if he/she were a mystery shopper. However, he should have refrained from embarrassing her by saying anything aloud about her specific request. More importantly, there are a number of other exchanges that should have occurred during the encounter. See the discussion of the second case (below) for a full description.

In the second case, if the patient is 18 years of age—or if she is younger than 18 years but the pharmacy has a collaborative practice agreement permitting the pharmacist to initiate emergency contraception—then the technician did the right thing.

The pharmacist can then explain emergency contraception, with emphasis on the timeline to assure its proper use, answer any questions, dispense the emergency contraceptives, describe how to take the pills, advise her of the chance of side effects, and provide written instructions. Other important information to convey:

- Emergency contraceptives are for emergency use only; recommend that she use another form of contraception if she is sexually active.
- The risk of pregnancy may be high soon after taking emergency contraceptives; they will not protect her against additional instances of intercourse.
- Emergency contraceptives do not protect against sexually transmitted diseases.
- Her next period may be a few days early or late.

The pharmacist may also try to determine whether she is a victim of sexual assault and make appropriate referrals. If that state does not permit pharmacists to initiate emergency contraception services for those under the age of 18 years, then the pharmacist should provide her with names, locations, and phone numbers of health care providers nearby who can help her. He/she should emphasize the urgency required, explaining that emergency contraceptives work best the earlier they are taken and they must be taken within 5 days—preferably within 3 days—of unprotected intercourse. Ideally, the pharmacist would contact the closest emergency contraception provider to advise them that a patient is being referred.

*Source: References 19 and 52.*

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# CE Assessment Questions

Instructions: For each question, circle the letter corresponding to the correct answer on the CE Examination Form. **Please review all of your answers to be sure you have marked the proper letter.** There is only one correct answer to each question.

## 1. Among the 60 million women in the United States of childbearing age:

- Fewer than half use some form of contraception.
- Nearly 1 million have an abortion to end an unintended pregnancy.
- Nearly 3 million have an unintended pregnancy.
- 10% have an unintended pregnancy.
- About 5% become pregnant each year.

## 2. A woman wishing to prevent pregnancy after unprotected intercourse can:

- Take RU-486.
- Take two doses of .75 mg of levonorgestrel at one time within 5 days.
- Double up on her regular oral contraceptives for the rest of the cycle.
- Ask her doctor for a prescription for Preven emergency contraceptives.
- Take emergency contraceptives if she misses a period.

## 3. The “morning-after” pill is a good name for emergency contraceptives because:

- It must be taken the morning after unprotected intercourse.
- It may be taken any morning within 5 days of unprotected intercourse.
- “Morning-after” pill is not a good name for emergency contraceptives.
- It should be taken the morning after a woman misses her period.
- It is taken in two doses—one on the morning after unprotected intercourse and the second dose the following morning.

## 4. Emergency contraception may be achieved:

- By taking methotrexate.
- By taking misoprostol to cause uterine contractions.
- By taking large doses of oral contraceptives.
- By expelling a fertilized egg from the uterine lining.
- In the doctor's office or clinic.

## 5. The mechanism of action of emergency contraceptives:

- Is the same in all women.
- Involves inhibiting or delaying the release of an egg from the ovary.
- Is to alter ovarian hormone levels when they are taken postovulation.
- Is the same as for abortifacients.
- Involves blocking the hormones necessary for maintaining a pregnancy.

## 6. The number one reason women ask for emergency contraceptives is:

- She missed two birth control pills in a row.
- She is 1 week late for her progestin-only contraceptive injection.
- She was forced to have unprotected sex.
- Her partner's condom ruptured during intercourse.
- She and her partner did not use any type of contraception.

## 7. Emergency contraceptives are most effective when:

- Two doses of levonorgestrel (0.75 mg each) are taken together.
- They are initiated 36 to 48 hours after unprotected intercourse.
- The first dose is taken within a week of unprotected intercourse.
- They are taken right after ovulation.
- Combination oral contraceptives are taken in high doses.

---

## 8. Regarding the efficacy of emergency contraceptives:

- a. The Yuzpe regimen is more effective than progestin-only emergency contraception.
- b. Combination oral contraceptives and progestin-only pills are equally effective.
- c. Progestin-only contraceptives are more effective than large doses of combination oral contraceptives.
- d. Either method is more effective in preventing pregnancy than routine use of traditional oral contraceptives.
- e. The risk of pregnancy is higher for those taking progestin-only emergency contraceptives compared with those taking combination oral contraceptives.

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## 9. Progestin-only emergency contraceptives are contraindicated in:

- a. Women with a personal or family history of blood clots.
- b. Women who are pregnant.
- c. Women who have frequent migraine headaches.
- d. Women with liver disease.
- e. There are no contraindications to using progestin-only emergency contraceptives.

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## 10. Combination emergency contraceptives:

- a. Have fewer side effects than progestin-only emergency contraceptives.
- b. Cause nausea in less than one quarter of women who take them.
- c. Cause vomiting in about half of women who take them.
- d. Cause nausea in twice as many women as progestin-only emergency contraceptives.
- e. Do not cause side effects because only two doses are taken.

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## 11. Progestin-only emergency contraceptives are unique because:

- a. They are the only contraceptive available OTC to anyone.
- b. They hold dual status, as both a prescription medicine and an OTC product for most women.

- c. They are the only oral contraceptive that contains levonorgestrel.
- d. They are OTC but must be kept behind the counter at the pharmacy.
- e. They may be sold to consumers aged 18 years or older in convenience stores.

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## 12. FDA stipulated that emergency contraceptives be kept behind the counter:

- a. To thwart shoplifting.
- b. To force users to register.
- c. To ensure some degree of emergency contraception counseling.
- d. To enforce distribution quotas.
- e. Because they are only available via prescription.

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## 13. Which is true regarding unintended pregnancies for teens?

- a. The American Academy of Pediatrics and the American College of Obstetricians and Gynecologists recommend against the use of emergency contraception in adolescents.
- b. Those younger than 18 years do not have OTC access to emergency contraceptives in most states.
- c. Nearly one quarter become pregnant before they reach the age of 20 years.
- d. Emergency contraceptives are contraindicated in this age group.
- e. They need parental consent to obtain emergency contraceptives.

---

## 14. Pharmacists may dispense progestin-only emergency contraceptives to any of the following except:

- a. An 18-year-old boy.
- b. Women aged 18 years or older without a prescription.
- c. The parent of a 15-year-old.
- d. A victim of sexual abuse who is over the age of 17 years.
- e. A 17-year-old girl without a prescription.

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**15. Demographic studies have shown that:**

- Only 10% of pregnancies among married women are unintended.
- Women without a high school diploma have nearly twice as many unintended births as college graduates.
- Unmarried cohabiting women are at high risk for unintended births.
- Unintended pregnancies occur 10 times more often in women below the poverty line than among those whose income is twice the poverty level.
- The majority of unintended pregnancies occur in teenagers.

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**16. The following forms of ID are acceptable to prove eligibility for OTC purchase of progestin-only emergency contraceptives except:**

- An expired U.S. passport.
- A student ID card with photo.
- A voter registration card.
- A foreign passport with temporary I-551 stamp (expired).
- A Native-American tribal ID document.

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**17. When a patient asks for the “morning-after” pill, the first thing the pharmacist should do is:**

- Ask whether the patient had unprotected intercourse within the past 24 hours.
- Explain how emergency contraception works.
- Check to see if emergency contraceptives are in stock.
- Ask the patient’s age to determine whether a prescription is required.
- Ask if the patient is pregnant.

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**18. When dispensing emergency contraceptives, the pharmacist should inform the patient that:**

- She should take a repeat dose if she vomits within 1 to 2 hours of taking the first dose.
- If she is already pregnant, the medication may harm her developing fetus.
- Taking additional pills will improve the medication’s efficacy.
- She should take a repeat dose if she vomits > 2 hours after taking the first dose.
- She will probably get her next period earlier than it is due.

**CE Credit:**

To obtain 3 hours of continuing education credit (0.3 CEUs) for “Emergency Contraception: The Pivotal Role of the Pharmacist,” complete the assessment exercise, fill out the “CE Examination Form” at the end of this publication, and return that page to APhA. A statement of CE credit will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before October 1, 2010, can receive credit.



The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The ACPE Universal Program Number assigned to the program by the accredited provider is: 202-000-07-220-H01.

“Emergency Contraception: The Pivotal Role of the Pharmacist” is a home-study continuing education program for pharmacists developed by the American Pharmacists Association and supported by an educational grant from Duramed Research, Inc.



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**19. Following emergency contraception, a woman’s menstrual period is likely to:**

- Be several days late.
- Return within 3 days of the anticipated date.
- Last significantly longer than usual.
- Be irregular for the ensuing few months.
- Be late if she took the emergency contraceptives early in her cycle.

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**20. In counseling a patient about emergency contraception, the pharmacist should:**

- Reassure her that she can use this method as often as needed.
- Recommend that another form of contraception be used routinely.
- Tell her that she is protected against becoming pregnant for the remainder of her current monthly cycle.
- Advise her that it is safe to have unprotected intercourse again within a few days.
- Tell her to wait until after her next period before resuming use of oral contraceptives.

# CE EXAMINATION FORM

## Emergency Contraception: The Pivotal Role of the Pharmacist

To receive **3.0** contact hours of continuing education credit (**0.3 CEUs**), please provide the following information:

- Type or print your name and address in the spaces provided.
- Mail this completed form for scoring to:  
American Pharmacists Association—CE Exam  
P.O. Box 791082  
Baltimore, MD 21279-1082
- The CE processing for grading the assessment instrument and issuing the Statement of Credit is supported by an educational grant from Duramed Research, Inc.

A Statement of Credit will be awarded for a passing grade of 70% or better. If you fail the exam, you may retake the exam once. If you do not pass the second time, you may no longer participate in this continuing pharmacy education program. Please allow 6 weeks for processing. Pharmacists who complete this exercise successfully before **October 1, 2010**, can receive credit.



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### PARTICIPANT INFORMATION

NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_

E-MAIL \_\_\_\_\_

WORK PHONE \_\_\_\_\_

HOME PHONE \_\_\_\_\_

How long did it take you to read the continuing education program and complete this test? \_\_\_\_\_Hours \_\_\_\_\_Minutes

My signature certifies that I have independently taken this CE Examination:

\_\_\_\_\_

### CE ASSESSMENT QUESTIONS—ANSWERS

Please circle your answers (one answer per question).

- |              |               |               |               |
|--------------|---------------|---------------|---------------|
| 1. a b c d e | 6. a b c d e  | 11. a b c d e | 16. a b c d e |
| 2. a b c d e | 7. a b c d e  | 12. a b c d e | 17. a b c d e |
| 3. a b c d e | 8. a b c d e  | 13. a b c d e | 18. a b c d e |
| 4. a b c d e | 9. a b c d e  | 14. a b c d e | 19. a b c d e |
| 5. a b c d e | 10. a b c d e | 15. a b c d e | 20. a b c d e |

### PROGRAM EVALUATION

#### PLEASE ANSWER EACH QUESTION.

	EXCELLENT			POOR	
1. Overall quality of the program	5	4	3	2	1
2. The program was relevant to pharmacy practice	5	4	3	2	1
3. Value of the content	5	4	3	2	1

#### PLEASE ANSWER EACH QUESTION MARKING WHETHER YOU AGREE OR DISAGREE.

	Agree	Disagree
4. The program met the stated learning objectives:		
• Define emergency contraception and describe how it works.	<input type="checkbox"/>	<input type="checkbox"/>
• Identify situations in which emergency contraception may be indicated.	<input type="checkbox"/>	<input type="checkbox"/>
• Describe methods of emergency contraception currently available.	<input type="checkbox"/>	<input type="checkbox"/>
• Discuss behind-the-counter and dual-status products.	<input type="checkbox"/>	<input type="checkbox"/>
• Discuss the role of the pharmacist in dispensing emergency contraceptives and counseling patients on their proper use.	<input type="checkbox"/>	<input type="checkbox"/>
5. The program increased my knowledge in the subject area.	<input type="checkbox"/>	<input type="checkbox"/>
6. The program did not promote a particular product or company.	<input type="checkbox"/>	<input type="checkbox"/>

#### Impact of the Activity

The information presented (check all that apply):

7.  Reinforced my current practice/treatment habits    Will improve my practice/patient outcomes    Provided new ideas or information I expect to use  
 Enhances my current knowledge base

8. Will the information presented cause you to make any changes in your practice?  Yes    No

9. How committed are you to making these changes? (Very committed) 5 4 3 2 1 (Not at all committed)

10. Do you feel future activities on this subject matter are necessary and/or important to your practice?  Yes    No

### Follow Up

As part of our ongoing quality-improvement effort, we would like to be able to contact you in the event we conduct a follow-up survey to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

- Yes, I am interested in participating in a follow-up survey.    No, I am not interested in participating in a follow-up survey.

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