



**American
Pharmaceutical
Association**

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*The National Professional
Society of Pharmacists*

September 8, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket 00D-1350

Dear Sir/Madam:

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, is pleased to submit comments on the Food and Drug Administration's (FDA) draft "Guidance for Industry: Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients." APhA's more than 50,000 members include practicing pharmacists, pharmaceutical scientists, pharmacy students, and pharmacy technicians.

The draft guidance is an important step in facilitating the proper use of combined oral contraceptives. Proper labeling for all prescription and over-the-counter drugs is essential for both healthcare providers and patients. Pharmacists utilize drug labeling as a daily part of their pharmacy practice. Pharmacists often refer to drug labeling for information on dosage, contraindications, drug interactions, and side effects; and as a handout to assist with patient counseling. Pharmacist/patient communication is vital to insure appropriate usage, patient safety, and maximum efficacy.

APhA appreciates the FDA's recognition of the need for uniform labeling for combined oral contraceptive products. The need for clear, concise, easy-to-read instructions for oral contraceptives is evident in the numerous studies that illustrate improper use of oral contraceptives. Perfect use of combined oral contraceptives have a pregnancy rate of only 0.1% or one pregnancy per 1,000 women in the first twelve months of use. However, the typical use pregnancy rate for combined oral contraceptives is 5% or 50 pregnancies per 1,000 women.¹ The significant increase in the typical use pregnancy rate can be attributed to inconsistent use of oral contraceptives, such as: missing pills, taking pills out of sequence, incorrectly switching between pill packs, taking periodic breaks from the pill, or stopping due to side effects.² Contraceptive failure has been linked to approximately one-half of unintended pregnancies each year in the United States.

¹ 65 Federal Register at 42,387.

² Zlidar, VM. Helping Women Use the Pill. Population Reports, Series A, No. 10. Johns Hopkins University School of Public Health, Population Information Program, 2000.

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APhA supports the FDA's attempt to develop a standard template for oral contraceptive labeling. Current patient insert labeling contains technical, difficult to understand language often compressed in a small font. Many patients find the insert difficult to understand and do not read it.³ Comprehensive information with specific instructions for patient use, as outlined in the draft guidance, when combined with pharmacist and consumer communication, will likely increase patient compliance and product effectiveness and reduce the number of unintended pregnancies. APhA shares the FDA's interest in the creation of user-friendly labeling that clearly outlines the benefits and risks of product use and specific instructions for use.

APhA also offers the following recommendations on the draft "Guidance for Industry: Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients."

Interactions with Other Medications

APhA recommends the FDA emphasize the potential interactions between antibiotics and oral contraceptives. Under "Patient Labeling," the draft guidance states, "Antibiotics are rarely a problem, but it is a good idea to use a backup method of birth control just in case."⁴ This statement, however, does not strongly portray the potential loss of effectiveness antibiotics may have on oral contraceptives. Although there is no conclusive scientific evidence that antibiotics in general reduce the effectiveness of oral contraceptives, antibiotics have been reported as a potential cause of unintended pregnancy in women utilizing oral contraceptives. As the guidance is currently written, patients may receive the impression that the risk of contraceptive failure is so minute that no backup method of birth control is required. In order to provide patients with the most protection, APhA recommends the following revision to the warning statement: "Antibiotics may make the pill less effective. To avoid unintentional pregnancy, use a backup method of birth control while taking antibiotics."

Emergency Contraception

In a 1997 *Federal Register* notice, the FDA officially declared common regimens of emergency contraception as safe and effective methods to prevent pregnancy. For several decades, combined oral contraceptives have been prescribed for the off-label use of emergency contraception. While the *Federal Register* notice encouraged manufacturers to submit new drug applications for this use, the FDA declined to require manufacturers to amend their labeling to include information regarding the use of oral contraceptives as emergency contraception.⁵

In the recently issued draft guidance, the "Labeling for Healthcare Providers" section does include information on oral contraceptives used as emergency contraception. However, the guidance is only a *recommendation* for manufacturers, leaving the inclusion of this information to the manufacturer's discretion. APhA strongly urges the FDA to include

³ Rubin, R. Millions Pay Price for Pill Misuse: Women Using the Oral Contraceptive Need Better, Simpler Information. USA Today, August 14, 2000.

⁴ Guidance for Industry: Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients. Food and Drug Administration, June 2000.

⁵ 62 Federal Register at 8,610.

additional information on emergency contraception in the guidance and mandate emergency contraception labeling on combined oral contraceptives. Specifically, APhA requests the FDA to:

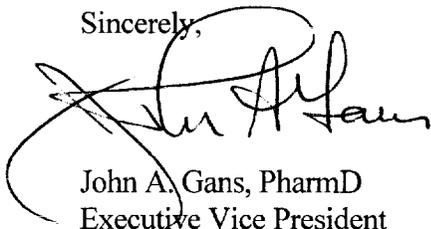
- Revise the “Labeling for Healthcare Providers” section to include emergency contraception as one of the indications for use, information on emergency contraception efficacy, and information on potential adverse experiences.
- Revise the “Patient Labeling” section to include instructions for use as an emergency contraceptive and information on potential adverse experiences.
- Include an updated list of combined oral contraceptives that may be used as an emergency contraceptive. (See example in Attachment A)

The use of emergency contraception after unprotected sex could significantly reduce the number of unintentional pregnancies and abortions in the United States. Unfortunately many women, and even some health care professionals, are not aware of the availability of emergency contraception or mistakenly believe that emergency contraception is an abortifacient. As part of a campaign to educate pharmacists, APhA recently released the *APhA Special Report: Emergency Contraception: The Pharmacist's Role*. (See Attachment B) While efforts by individuals, organizations, and the media can educate health care professionals and the public, only written information included with the product can provide pharmacists and other health care professionals with the information and instructions when it is most important.

In conclusion, APhA fully supports the intent of the draft guidance. Measures to create user-friendly product labeling and increase patient use of medications are a priority for this Association and our members. Again, we ask the FDA to consider strengthening the guidance's warning on potential interactions with antibiotics, and to mandate the use of emergency contraception labeling on combined oral contraceptives.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, APhA's Group Director of Policy and Advocacy, at 202-429-7533 or Susan K. Bishop, APhA's Manager of Regulatory Affairs and Political Action at 202-429-7538 with any questions.

Sincerely,



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Dosages for Emergency Contraceptive Pills

<u>Combined Oral Contraceptive</u>	<u>First Dose—within 72 hours</u>	<u>Second Dose—12 hours later</u>
Alesse	5 pink pills	5 pink pills
Eugynon	2 white pills	2 white pills
Levlen	4 light-orange pills	4 light-orange pills
Levlite	5 pink pills	5 pink pills
Levora	4 white pills	4 white pills
Lo-Femenal	4 white pills	4 white pills
Microgynon	4 yellow pills	4 yellow pills
Lo-Ovral	4 white pills	4 white pills
Nordette	4 light-orange pills	4 light-orange pills
Ovidon	2 pills	2 pills
Ovral	2 white pills	2 white pills
Rigevidon	4 pills	4 pills
Tri-Levlen	4 yellow pills	4 yellow pills
Triphasil	4 yellow pills	4 yellow pills
Trivora	4 pink pills	4 pink pills

Source: Zlidar, VM. Helping Women Use the Pill. Population Reports, Series A, No. 10. Johns Hopkins University School of Public Health, Population Information Program, 2000.

A_{PhA} Special Report

A Continuing Education Program for Pharmacists

Emergency

Contraception:

The Pharmacist's

Role



American
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*The National Professional
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Program Preview

There are approximately 3 million unintended pregnancies in the United States each year. About half occur because a contraceptive has failed, and nearly 50% of them end in abortion. Emergency contraception, used soon after sexual intercourse, can prevent unwanted pregnancy.

Oral contraceptives have been used "off label" as emergency contraception by at least 225,000 women in the United States over the past few decades. Unfortunately, there are substantial barriers to more widespread use of emergency contraception. Many women are unaware of its existence, and many health care professionals are uninformed about the practical aspects of providing it. Misconceptions persist about how emergency contraception works, particularly the misconception that emergency contraception acts as an abortifacient. Until recently, there were no products designed, approved, and labeled specifically for use as emergency contraception.

In the past few years, educational campaigns have been launched to increase public awareness and health professional knowledge about emergency contraception. The Food and Drug Administration has declared a number of oral contraceptives to be safe and effective for use as emergency contraception. Two pharmaceutical products packaged and marketed specifically for use as emergency contraception (Preven and Plan B) recently have become available. With these developments, the use of emergency contraception is increasing and likely will continue to expand. It is important that pharmacists be prepared to help women use it effectively.

This Special Report describes methods of emergency contraception available for use in the United States and compares their mechanisms of action, efficacy, and safety. It also explores the roles that pharmacists can assume in providing emergency contraception. The possibilities range from effective counseling for women who receive a prescription for emergency contraception to writing that prescription under a collaborative practice agreement. Pharmacists are in a good position to educate both their patients and other health care professionals by conveying accurate information about emergency contraception.

Learning Objectives

After reading this article, the pharmacist should be able to:

1. Define emergency contraception and describe how emergency contraception works.
2. Identify situations in which emergency contraception may be indicated.
3. Describe the methods of emergency contraception available in the United States.
4. Compare the efficacy and adverse effects of the two options for oral emergency contraception: the Yuzpe regimen (e.g., Preven) and levonorgestrel alone (e.g., Plan B).
5. Discuss important roles for pharmacists in counseling and educating patients, increasing awareness and understanding of emergency contraception among consumers and health care providers, and possibly prescribing emergency contraceptives under collaborative practice agreements.

Introduction

More than 6 million women become pregnant in the United States each year. Approximately half of these pregnancies are unintended—either mistimed or unwanted. Unfortunately, nearly 50% of unintended pregnancies end in abortion.¹ It has been estimated that widespread use of emergency contraception could prevent 1 million abortions and 2 million unintended pregnancies each year in the United States.²

Emergency contraception may be defined as the use of a drug or device soon after sexual intercourse to prevent pregnancy.³ The first emergency contraception method to be described used high-dose estrogen, but this regimen has been abandoned because of a high incidence of intolerable adverse effects (especially nausea and vomiting). Danazol also has been used, but its efficacy is questionable.⁴ The regimens currently favored use oral contraceptive combinations containing high doses of estrogen and progestin (ethinyl estradiol plus levonorgestrel) or progestin (levonorgestrel) alone. Two new products (Preven and Plan B) are packaged and marketed specifically for use as emergency contraception.

Postcoital insertion of a copper-releasing intrauterine contraceptive device (IUD) is a highly effective but far less convenient method of emergency contraception.⁵ IUDs are available only through health care providers and must be inserted by a health care provider. The IUD is not recommended for use by women at high risk for sexually transmitted infections (e.g., women with multiple sex partners or women whose partners have multiple sex partners).⁶ The emphasis of this Special Report is on orally administered emergency contraception.

Although orally administered emergency contraception is often referred to as the “morning-after pill,” this term can be misleading. The emergency contraception regimens often involve several tablets administered in two doses, not a single “pill” administered in a single dose. Also, the term “morning-after pill” (as well as the term “postcoital contraception”) may lead some women, and even health professionals, to believe that emergency contraception can be used only on the morning after intercourse.^{4,7} In fact, women can administer the first dose of an oral emergency contraceptive as late as 72 hours after unprotected intercourse.⁸ An IUD can be inserted for use as an emergency contraceptive up to 5 days after unprotected intercourse.⁴

Evolution of Emergency Contraception

Use of an oral contraceptive combination for emergency contraception, otherwise known as the Yuzpe regimen, was first described by Albert Yuzpe and colleagues in 1974.⁹ That study employed a dose of ethinyl estradiol 100 µg and DL-norgestrel 0.1 mg (administered as

two tablets each containing ethinyl estradiol 50 µg and DL-norgestrel 0.5 mg) taken within 72 hours of unprotected sexual intercourse, with a second dose taken 12 hours later.^{8,10} Levonorgestrel is the active ingredient in DL-norgestrel (the amount of levonorgestrel in each dose is half the amount of norgestrel), so dosing approximately equivalent to the regimen studied by Yuzpe et al can be obtained using a number of oral contraceptives on an “off-label” basis.⁸ Over the last 2 decades, the Yuzpe regimen has been used by at least 225,000 American women treated primarily in hospital emergency rooms, reproductive health clinics, and university health centers.¹¹

More widespread use of emergency contraception has been impeded in part because the public is largely unaware of it. In 1994, a Kaiser Family Foundation national survey of approximately 2000 Americans found that 55% of respondents had heard about the morning-after pill. However, only 9% of them were aware that emergency contraception could be used up to 72 hours after unprotected intercourse, and only 1% reported ever using emergency contraception. Once informed about emergency contraception, 47% of women at risk for unintended pregnancy reported that they would be very likely to consider using the method if needed. In 1995, a survey of 307 obstetrician-gynecologists found that although the vast majority were familiar with emergency contraception and considered it safe and effective, only 7% of them discussed it with patients during routine counseling about contraception. This is noteworthy because more than 80% of women at risk for unplanned pregnancy say that they rely on their health care provider for information about birth control.¹²

In the past, the underuse of emergency contraception was almost certainly due in part to the fact that no drug products were approved by the Food and Drug Administration (FDA) specifically for that indication.¹³ A number of key events in recent years increased awareness about emergency contraception and led to the marketing of FDA-approved products intended for that purpose:

- In 1994, the Center for Reproductive Law and Policy filed a citizen petition asking the FDA to require certain manufacturers of oral contraceptives to provide information in their product labeling about the use of their products as emergency contraception.¹¹
- In 1996, the Reproductive Health Technologies Project and the Office of Population Research at Princeton University established a national toll-free telephone hot line (1-888-NOT-2-LATE) providing consumer-oriented information about and referrals for emergency contraception. Soon after, they also launched a national media campaign to increase public awareness of emergency contraception.¹⁴
- In 1997, in response to the citizen petition from the Center for Reproductive Law and Policy, the FDA concluded that certain oral contraceptive combinations containing ethinyl estradiol and norgestrel or levonorgestrel (Ovral, Lo/Ovral, Nordette, Levlen, Triphasil, Tri-Levlen) are safe and effective

for emergency contraception. The agency requested the submission of new drug applications for this indication.¹¹

- In the fall of 1998, the Preven Emergency Contraceptive Kit, a product based on the Yuzpe regimen, was approved specifically for use as emergency contraception.
- In the summer of 1999, Plan B, a progestin-only regimen containing levonorgestrel, was approved for use as an emergency contraceptive.

A repeat survey by the Kaiser Family Foundation in 1997 found that awareness of emergency contraception had grown significantly among the women polled (66% in 1997 vs 61% in 1994). Most had learned about it through the media rather than from a health care provider. Only 18% of women at risk for unintended pregnancy who were aware of emergency contraception knew that it is available in the United States. Prescribing of emergency contraception had increased substantially, bolstered by the FDA's endorsement of some oral contraceptive combinations as safe and effective for this use. Physicians reported that they would be more likely to prescribe emergency contraception if the drugs were packaged and marketed specifically for that use.¹³

The use of emergency contraception is endorsed by a number of national and international organizations. The American College of

Obstetrics and Gynecology has published an evidence-based clinical practice guideline to assist clinicians in the use of emergency contraception.⁸ Planned Parenthood clinics provide emergency contraception to some clients for later use, allow oral products to be prescribed over the phone to established clients, and offer IUD insertion for emergency contraception.^{4,15} Federally funded Title X family planning clinics also are authorized to provide emergency contraception.⁴ Emergency contraceptives are included on the Essential Drugs List of the World Health Organization.

The Menstrual Cycle, Pregnancy, and Emergency Contraception

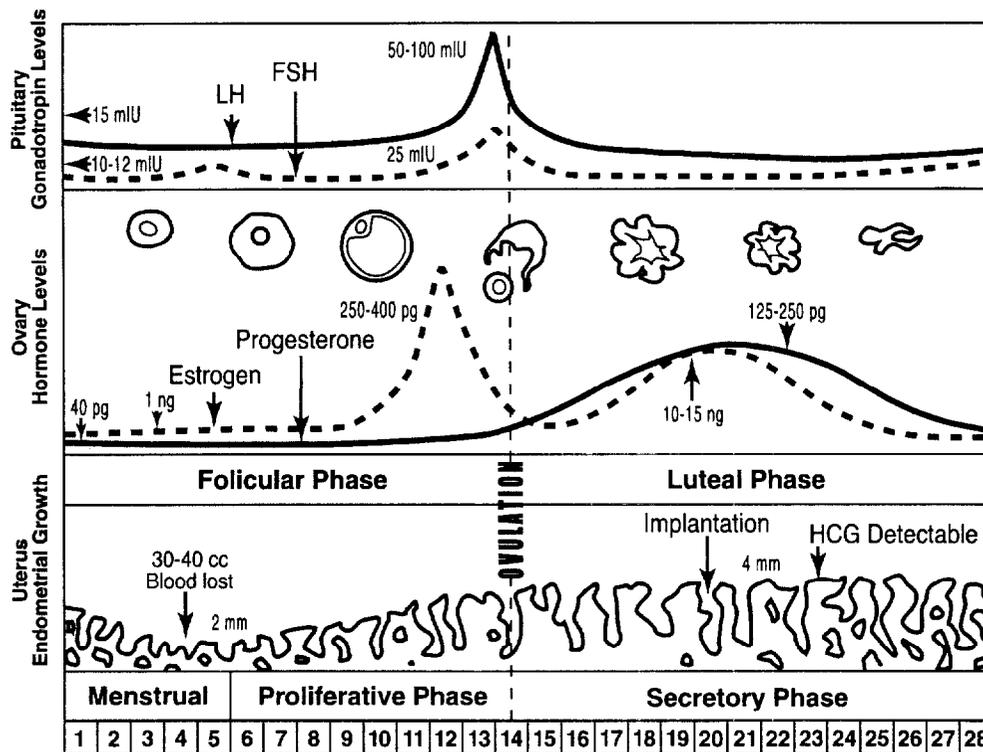
Knowledge of the menstrual cycle and the process that leads to pregnancy is important for understanding how emergency contraception works and when it is needed most.

The Menstrual Cycle

The menstrual cycle is a complex series of events (Figure 1) that culminates in the release of a single egg (oocyte) from the

Figure 1.

Events in the Menstrual Cycle



ovaries each month during ovulation. The length of the normal menstrual cycle ranges from 23 to 35 days. It varies from woman to woman and may even vary from cycle to cycle. Each cycle has four phases: follicular, ovulatory, luteal, and menstrual.¹⁶

Events in the menstrual cycle are orchestrated by the release of hormones from the hypothalamus, pituitary gland, and ovaries. Specifically, gonadotropin-releasing hormone from the hypothalamus stimulates the pituitary gland to produce two gonadotropins: follicle-stimulating hormone (FSH) and luteinizing hormone (LH). In the follicular phase, FSH stimulates the growth of many ovarian follicles. By the seventh day of the cycle, one of them becomes the dominant follicle. The dominant follicle begins to mature and starts to produce estrogen. Ovarian estrogen production increases the thickness of the endometrium of the uterus, making it receptive to possible implantation of a fertilized egg. The length of the follicular phase is variable and can last from 10 to 17 days.¹⁶

Increasing ovarian estrogen production regulates the production of FSH and LH by the pituitary gland in a feedback loop. The transition from the follicular phase to the ovulatory phase is triggered by high levels of estrogen. The pituitary responds to a critical level of estrogen with a surge of LH and FSH. Within 32 to 44 hours after the onset of the LH surge, the dominant follicle ruptures and the egg is released.¹⁶

The release of the egg from the follicle marks the onset of the luteal phase. The egg passes into the fallopian tube where fertilization occurs if viable sperm are present. The egg is viable for fertilization only for up to a day after release from the follicle. During the luteal phase, progesterone produced by the ovaries causes secretory changes to the endometrium. Ovarian progesterone production peaks 7 to 8 days after the LH surge. If the egg has been fertilized, cell division begins, and the resulting blastocyst travels to the uterus and becomes implanted in the endometrium. If fertilization and implantation do not occur, the luteal phase lasts approximately 14 days. Then progesterone levels decline, triggering the onset of menses. The menstrual phase generally lasts from 4 to 6 days.¹⁶

Pregnancy

Implantation of the blastocyst in the endometrium marks the beginning of pregnancy.¹⁷ Many events must occur with precise timing for a pregnancy to be established. First, sperm and egg must mature normally. Sperm must be released in the woman's vagina shortly before ovulation occurs. The sperm must then travel through the vagina, cervix, and uterus to the fallopian tubes. During this process, the sperm must undergo final maturation necessary for fusion with and fertilization of the egg that has traveled from the ovary. After fertilization, the egg must mature to the blastocyst stage, travel to the uterus, and implant successfully in the endometrium.¹⁷

Fertilization of an egg can occur only around the time of ovulation. It is most likely to occur if sperm are present in the female

upper reproductive tract when ovulation occurs. Since sperm can remain viable for at least 3 days, and perhaps as long as 5 days, pregnancy is most probable if sexual intercourse occurs during the days directly preceding ovulation.^{16,18} A study of women trying to become pregnant found that the fertile period lasts about 6 days, ending on the day of ovulation. The likelihood of pregnancy increased from 8% following intercourse 6 days before ovulation to 36% following intercourse on the day of ovulation.¹⁸ Other studies have found that the likelihood of pregnancy is very small when sexual intercourse follows ovulation.¹⁹

Mechanism of Action of Emergency Contraceptives

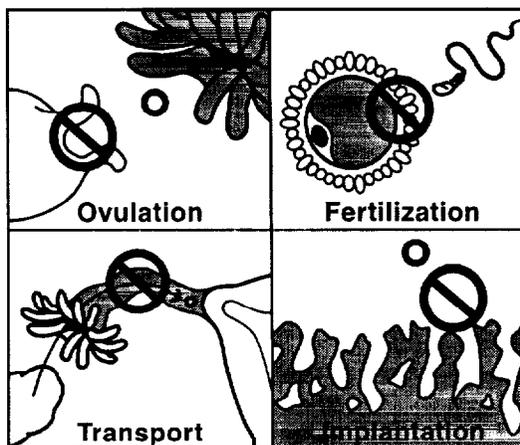
Like oral contraceptives that are taken on a daily basis, emergency contraceptives might prevent pregnancy by inhibiting any of the events necessary for a pregnancy to become established (Figure 2):

1. Ovulation (by suppressing the midcycle surge in LH that is necessary for final follicular growth and ovulation);
2. Fertilization (by interfering with the movement of sperm or egg);
3. Transport of the fertilized egg to the uterus; or
4. Implantation of the blastocyst in the endometrium (by creating changes that make the endometrium unreceptive to implantation).^{3,4,8,10}

Because emergency contraceptives act before implantation and cannot disrupt an established pregnancy, they are not considered to be abortifacients.^{3,20} In contrast, the progesterone antagonist mifepristone (RU-486) is capable of interrupting an established

Figure 2.

Possible Mechanisms of Action of Emergency Contraception



pregnancy and is used commonly in some European countries and China as an abortifacient early during pregnancy.²¹

The efficacy of emergency contraception is greatest when treatment is initiated soon after unprotected intercourse; the efficacy then diminishes in an apparently linear fashion as the time period between intercourse and administration of the hormonal agents increases.^{10,22} The regimen becomes completely ineffective by day 6 or 7 following intercourse, when implantation usually occurs.¹⁰ In almost all studies, the first dose of emergency contraception was administered within 72 hours after unprotected intercourse.⁸

The next menstrual period occurs at the expected time in the majority of women who use emergency contraception. The onset of menstrual bleeding may occur 3 to 7 days earlier than expected if the treatment is given before ovulation, or later than expected if treatment is administered after ovulation.⁸ Up to 98% of women will menstruate within 21 days of using oral emergency contraceptives.⁸ The possibility of pregnancy should be considered if menstruation does not occur within 21 days of treatment.⁸

Indications for Emergency Contraception

Any woman of reproductive age who has had unprotected sexual intercourse in the past 72 hours (either consensual or because of sexual assault) is a candidate for emergency contraception.⁸ Specific indications for emergency contraception are listed in Table 1. The "typical" woman seeking emergency contraception is less than 25 years of age, has been sexually active for several years, has used some form of contraception before, and has never been pregnant.⁸ With the recent availability of specially packaged products, emergency contraception might be used by an estimated 5 million American women each year.²³

Half of women who become pregnant unintentionally report using contraception during the month that they became pregnant.¹ In two recent surveys, emergency contraception was requested most often because a primary contraceptive method, usually a condom, was known or suspected to have failed.^{24,25} However, the need for emergency contraception is not necessarily limited to women using barrier methods of contraception, for which failure may be readily apparent. The risk of pregnancy increases during the week after a woman misses two consecutive doses of an oral contraceptive, and a back-up method of contraception is recommended during this week.²⁶ As many as one woman in five misses at least two doses during a monthly cycle.²⁷

Although women are most likely to become pregnant when intercourse occurs during the 6 days leading up to and including ovulation, emergency contraceptives can be recommended for unprotected intercourse at any time during the menstrual cycle. Some women may elect not to use emergency contraception if inter-

Table 1.

Indications for Emergency Contraception

- No contraception was used when intercourse took place.
- A male condom slipped, broke, or leaked.
- A diaphragm or cervical cap was inserted incorrectly, became dislodged during intercourse, was removed too early, or was found to be torn.
- One or more oral contraceptive combination tablets was missed before or after the hormone-free interval, thereby prolonging the hormone-free interval beyond 7 days.
- A woman missed two or more active oral contraceptive combination tablets in a row during the pill cycle.
- A woman missed one or more progestin-only contraceptive tablets.
- A female condom was inserted or removed incorrectly, or the penis was inserted between the female condom and the vaginal wall, leading to intravaginal ejaculation.
- The couple erred in practicing coitus interruptus.
- The couple erred in practicing periodic abstinence.
- An IUD was partially or totally expelled.
- A woman was exposed to a possible teratogen such as a live vaccine, tretinoin, or a cytotoxic agent when she was not protected by effective contraception.
- A woman was sexually assaulted.
- A woman was more than 2 weeks late for a contraceptive injection.

Source: References 4 and 15.

course has occurred at a time in their cycle that is associated with a low risk of pregnancy. Women who miss doses of oral contraceptives are an exception to this rule because they do not have a true menstrual cycle. Their risk of pregnancy is highest if they miss two or more tablets during the first or third weeks of the drug cycle (i.e., if the 7-day hormone-free interval is extended).¹⁵

Because timing of emergency contraception administration is crucial, many family planning experts believe that women should have access to emergency contraceptives before they need them (i.e., women should receive a prescription or a supply of emergency contraceptives in advance, to keep at home). They advocate providing emergency contraception routinely to sexually active women receiving regular gynecologic care, contraception, or treatment for a sexually transmitted infection.^{2,5} Glasier and Baird²⁸ evaluated the feasibility of giving women a supply of emergency hormonal contraceptive tablets to use as needed in the future, comparing the habits of these women with a control group of women who could obtain emergency contraception only after a visit to their physician. They found that providing women with a supply of emergency contraceptives to use as needed was safe. Women used the tablets correctly when they had written instructions to follow and did not use them excessively; having the tablets on hand did not change the way they used other contraceptives.

Oral Agents for Emergency Contraception

Preven and Plan B (Table 2) are hormonal contraceptives packaged specifically for use as emergency contraception. Both products are approved by the FDA for the prevention of pregnancy after known or suspected contraceptive failure or unprotected intercourse. Despite the availability of products designated specifically for emergency contraception, it still is permissible to provide regular oral contraceptives for use as emergency contraception.

Preven

The Preven Emergency Contraceptive Kit contains four blue tablets, each containing ethinyl estradiol 50 µg and levonorgestrel 0.25 mg (the equivalent of four tablets of the oral contraceptive Ovral).²⁹ Two tablets are taken initially, followed by a second dose of two tablets 12 hours later (i.e., the Yuzpe regimen). The kit also contains a patient information booklet and a urine pregnancy test, which is intended to determine whether the woman is already pregnant from intercourse that occurred earlier during the current menstrual cycle or during the previous cycle. The patient informa-

tion advises women who obtain a positive pregnancy test result not to take the tablets in the Preven kit.

The presence of a pregnancy test in the Preven kit concerns some reproductive health experts. They feel it serves no immediate purpose, because women do not need to undergo pregnancy testing before using emergency contraception.⁸ They also fear that including the test in the Preven kit might deter some women from using the emergency contraceptive tablets.³¹ For example, women might believe that emergency contraceptives could harm the fetus if they are already pregnant (this is not the case; see Teratogenicity section).³¹ Women with limited literacy might find the instructions in the kit confusing, become discouraged, and give up before taking the emergency contraceptives. Women with a negative test result could conclude wrongly that they have no need for emergency contraception.

The average wholesale price of the Preven Emergency Contraceptive Kit is \$19.94. This compares with an average wholesale price of approximately \$6.00 for four tablets of Ovral or \$25 to \$30 for an entire 1-month packet of oral contraceptive combinations.³²

Plan B

Plan B provides two white tablets, each containing levonorgestrel 0.75 mg, in an aluminum foil blister packet about the size of a woman's cosmetic compact.³⁰ The first tablet is taken within

Table 2.

Comparison of Preven and Plan B

Characteristic	Preven (Gynetics)	Plan B (Women's Capital Corporation)
Product Description	<ul style="list-style-type: none"> Kit containing four tablets, a patient information booklet, and a urine pregnancy test Each tablet contains ethinyl estradiol 50 µg and levonorgestrel 0.25 mg 	<ul style="list-style-type: none"> Package the size of a woman's cosmetic compact containing a blister packet of two tablets Each tablet contains levonorgestrel 0.75 mg
Dosage	<ul style="list-style-type: none"> Two tablets as soon as possible within 72 hr of unprotected intercourse, followed by two tablets 12 hr later Contact health care provider if vomiting occurs within 1 hr of taking either dose 	<ul style="list-style-type: none"> One tablet as soon as possible within 72 hr of unprotected intercourse, followed by second tablet 12 hr later Contact health care provider if vomiting occurs within 1 hr of taking either dose
Efficacy	<ul style="list-style-type: none"> Reduces expected number of pregnancies by 75% 	<ul style="list-style-type: none"> Reduces expected number of pregnancies by 89%
Drug Interactions ^a	<ul style="list-style-type: none"> Potential increase in estrogen adverse effects with vitamin C Potential decrease in efficacy with cytochrome P-450 3A4 enzyme inducers Potential decrease in efficacy with ritonavir, nelfinavir, and topiramate Some antibiotics may potentially decrease efficacy by interrupting enterohepatic recycling of estrogen 	<ul style="list-style-type: none"> Potential decrease in efficacy with cytochrome P-450 3A4 enzyme inducers like carbamazepine, phenytoin, barbiturates, and rifampin

^aNo formal drug-drug interaction studies have been performed with either product.

Source: References 22, 29, 30.

72 hours of unprotected intercourse, and the second tablet is taken 12 hours later. The levonorgestrel regimen in Plan B is equivalent to two 20-tablet doses of the progestin-only oral contraceptive Ovrette. No pregnancy test is packaged with Plan B.

Plan B initially was available only through Planned Parenthood and other family planning clinics, as well as some pharmacies in Washington State under collaborative practice agreements. Availability to other pharmacies is expected sometime during 2000 (personal communication, Christine Dilks, Women's Capital Corporation, Bellevue, WA, December 1, 1999).

At an average wholesale price of \$21.95, the cost of Plan B compares favorably with that of Preven and is one third the cost of dispensing two packs of Ovrette (average wholesale price \$59.10).³²

Oral Contraceptives

Oral contraceptives that can be used for emergency contraception are listed in Table 3. The doses of oral contraceptive combinations listed in Table 3 approximate the amount of ethinyl estradiol and DL norgestrel used in the regimen originally described by Yuzpe et al.⁸ However, formulations that provide 120 µg of ethinyl estradiol per dose may cause more nausea than formulations that provide 100 µg of ethinyl estradiol per dose.³⁴

When oral contraceptives are prescribed and dispensed for use as emergency contraception, it is important that the product be identified clearly and that the patient be instructed carefully about the number and color of tablets required for each dose.⁴ It is also important for women to receive written information (Appendix A), because patient information about emergency contraception is not provided by the manufacturers of oral contraceptives. Unless they are repack-

aged, triphasic formulations may not be the best choice for use as emergency contraceptives because patients can become confused and take the wrong strength of tablet.³⁴ Similarly, if the tablets will not be repackaged, it is preferable to prescribe and dispense a 21-day pack (rather than a 28-day pack with placebo tablets) so that women cannot take the inert tablets in error. When Ovrette is used as emergency contraception, it is important to emphasize to women that it really is correct and safe to take 20 tablets for each dose.¹⁵

Under certain circumstances, it may be acceptable for pharmacies to repackage oral contraceptives in bulk for dispensing by clinics as emergency contraception. However, before engaging in such practice, the pharmacist should determine whether this activity would make the pharmacy qualify as a drug repackager, wholesaler, or manufacturer under state or federal regulations.³⁵

Efficacy of Oral Emergency Contraception

Studying the efficacy of emergency contraceptives requires a different research and analysis approach than that used for other contraceptive methods. Treatment cannot be compared with placebo because the inclusion of a placebo group in such studies is unethical. Most women probably would not become pregnant from the single act of intercourse that led them to enroll in a study evaluating emergency contraception.^{3,5} Because the risk of pregnancy varies during the days leading up to ovulation, efficacy rates depend on the specific day of the cycle that the women in the study had unprotected intercourse. When comparing different studies, the expected num-

Table 3.

Oral Contraceptives That Can Be Used for Emergency Contraception

Brand Name	Manufacturer	No. and Color of Tablets per Dose ^a	Ethinyl Estradiol per Dose (µg)	Levonorgestrel per Dose (mg) ^a
Allesse	Wyeth-Ayerst	5 pink tablets	100	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Levlite	Berlex	5 pink tablets	100	0.50
Levora	Watson	4 white tablets	120	0.60
Lo/Ovral	Wyeth-Ayerst	4 white tablets	120	0.60 ^b
Nordette	Wyeth-Ayerst	4 light-orange tablets	120	0.60
Ovral	Wyeth-Ayerst	2 white tablets	100	0.50 ^b
Ovrette	Wyeth-Ayerst	20 yellow tablets	0	0.75 ^b
Tri-Levlen	Berlex	4 yellow tablets	120	0.50
Triphasil	Wyeth-Ayerst	4 yellow tablets	120	0.50
Trivora	Watson	4 pink tablets	120	0.50

^aThe treatment schedule is initial dose within 72 hours after unprotected intercourse and second dose 12 hours later.

^bThe progestin in Lo/Ovral, Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which is bioactive (levonorgestrel); the amount of norgestrel in each dose is twice the amount of levonorgestrel.

Source: References 8, 10, and 33.

ber of pregnancies is calculated by considering the number of women having unprotected intercourse on each day of the cycle and the probability of becoming pregnant on that day.⁴

The most recent estimate of efficacy for the Yuzpe regimen comes from Trussell et al.³⁶ Using the comparative methods outlined earlier, they pooled data from eight studies that included information about the number of women treated and the number of pregnancies that occurred based on the cycle day of unprotected intercourse relative to the expected day of ovulation. Trussell et al compared these pregnancy rates with pooled data from studies that determined pregnancy rates based on the cycle day relative to ovulation in women not using contraception. They estimated that the Yuzpe regimen reduces the risk of pregnancy by 74.1% (95% confidence interval [CI] = 62.9%, 79.2%). In other words, the use of this regimen by 100 women after a single act of unprotected intercourse would reduce the expected number of pregnancies from eight to two.²⁹

Strong evidence for the efficacy of levonorgestrel alone as an emergency contraceptive comes from an international World Health Organization study that randomized almost 2000 women to receive two doses of levonorgestrel 0.75 mg 12 hours apart or the Yuzpe regimen.²² The study enrolled women who had sexual intercourse only once within 72 hours of treatment. Nearly half (45%) of the women in each group entered the study because a barrier method of contraception had failed. Women in the study were relatively young (mean age 27 years), and approximately 80% had never used emergency contraception before.

Based on intent-to-treat analysis, the pregnancy rate in the World Health Organization study was 1.1% with levonorgestrel alone and 3.2% with the Yuzpe regimen.²² The relative risk of pregnancy was 0.36 with levonorgestrel compared with the Yuzpe regimen (95% CI = 0.18, 0.70). When pregnancy rates for each treatment were compared with expected pregnancy rates without emergency contraception, it was found that levonorgestrel and the Yuzpe regimen prevented 85% and 57% of pregnancies, respectively. For levonorgestrel alone, these data mean that the use of this regimen by 100 women after a single act of unprotected intercourse would reduce the expected number of pregnancies from eight to one.³⁰

The World Health Organization study also found that emergency contraception was significantly more effective the earlier it was used within the 72-hour interval. For levonorgestrel alone, the pregnancy prevention rate was 95% when treatment was begun within the first 24 hours, 85% when begun within 25 to 48 hours, and 58% when begun within 49 to 72 hours after unprotected intercourse.²² Corresponding pregnancy prevention rates for the Yuzpe regimen were 77%, 36%, and 31%, respectively. Delaying the first dose by 12 hours increased the odds of pregnancy by 50%.³⁷ Based on the World Health Organization study results, experts now recommend that the initial dose of emergency contraception be taken as soon as it is practical to do so.²²

Safety of Oral Emergency Contraceptives

Adverse Effects

Nausea and vomiting are common adverse effects of the Yuzpe regimen. Although the prophylactic use of an antiemetic is routinely recommended to reduce the risk of nausea and vomiting with the Yuzpe regimen, it was not until recently that an antiemetic was shown to be effective for this indication.⁴ Raymond et al³⁸ compared a single dose of meclizine 50 mg 1 hour before the first dose of the Yuzpe regimen with placebo and no pretreatment. The incidence of nausea was significantly lower with meclizine (47% vs 64% with either placebo or no pretreatment; relative risk 0.7; 95% CI = 0.6, 0.9). The severity of nausea and the incidence of vomiting also were reduced significantly with meclizine pretreatment. Recommended antiemetic regimens for preventing nausea and vomiting with the Yuzpe regimen are listed in Table 4.

Other common adverse effects of the Yuzpe regimen include fatigue, breast tenderness, headache, abdominal pain, and dizziness. These symptoms usually resolve within several days of treatment.⁴

Levonorgestrel alone is better tolerated than the Yuzpe regimen. In the large World Health Organization study comparing levonorgestrel with the Yuzpe regimen, levonorgestrel alone caused significantly less nausea (23% vs 51%), vomiting (6% vs 19%), dizziness (11% vs 17%), and fatigue (17% vs 29%) than the combination regimen.²² The routine use of an antiemetic is not recommended before women take a dose of Plan B.

Irregular vaginal bleeding or spotting may occur subsequent to emergency contraceptive use.^{29,30} These effects usually are temporary and do not indicate any serious problems. The menstrual flow of the period following emergency contraceptive use may be heavier or lighter than usual. In more than 90% of cases, menses will be of normal duration for the patient.⁸

Cautions

Ethinyl estradiol in oral contraceptive combinations causes a small dose-related increase in the risk of thrombosis and ischemic stroke.¹⁰ Although the Yuzpe regimen contains relatively large doses of ethinyl estradiol, they are given over a very short period of time and few serious adverse events have been reported. The British Medicines Control Agency reports that only three cases of thromboembolism and three cases of stroke were reported out of more than 4 million courses of emergency contraception given over a period of 13 years.³ Only one of these reactions occurred close enough to the time of administration to be considered drug related.¹¹ A case-control study evaluated the outcome of over 100,000 prescriptions for the Yuzpe regimen in the British General Practice Research Database. It found no measurable increased risk of thromboembolism.⁴⁰ In a study of

11 healthy volunteers, the Yuzpe regimen did not affect clotting factors.⁴¹ Despite these findings, the patient product labeling for Preven recommends against use by women with a history of thromboembolic disease or stroke.²⁹ The use of levonorgestrel alone may be preferred in women with a history of these conditions.⁴

Recommendations about the safety of the Yuzpe regimen for women with other contraindications to continuous use of oral contraceptive combinations are not consistent. In the view of some experts, the benefits of using emergency contraception outweigh the potential risks in women with contraindications such as a history of heart disease, acute focal migraine, or severe liver disease.⁴ Nonetheless, the patient product labeling for Preven recommends against use by women with most contraindications to oral contraceptive combinations.²⁹

Contraindications to the use of Plan B are the same as those for progestin-only oral contraceptives: pregnancy, undiagnosed abnormal genital bleeding, and a history of allergy to levonorgestrel. Women with diabetes should monitor their blood glucose concentrations more carefully while they are taking Plan B because its effects on carbohydrate metabolism are unknown and progestin-only contraceptives are known to cause a small decrease in glucose tolerance.³⁰

Teratogenicity

Information about the potential teratogenicity of emergency contraceptives can be extrapolated from data evaluating the teratogenicity of oral contraceptives. The regular use of oral contraceptives early in pregnancy has not been found to be harmful to the fetus.⁸ In fact, warnings about the potential teratogenicity of oral contraceptive combinations were removed from product labeling some years ago because studies have failed to demonstrate an adverse effect on the fetus when oral contraceptives are taken inadvertently early in pregnancy.¹¹ Although product labeling for Preven and Plan B list known or suspected pregnancy as a contraindication for use, the primary reason for not using either method during pregnancy is lack of efficacy rather than concern about teratogenicity.^{4,29,30}

Drug Interactions

Drug interaction studies have not been performed with either the Yuzpe regimen or levonorgestrel alone.^{29,30} The potential for drug interactions should be considered based on what is known about drug interactions with oral contraceptive combinations and progestin-only oral contraceptives. However, it is not known if these

Table 4.

Antiemetics for Prevention of Nausea and Vomiting With the Yuzpe Regimen of Emergency Contraception

Drug (Brand Name)	Usual Dosage	Timing of Administration ^a
Nonprescription drugs		
Cyclizine hydrochloride (Marezine)	One 50-mg tablet	30 min before first dose; repeat as needed every 4–6 hr
Dimenhydrinate (Dramamine)	One or two 50-mg tablets or 20–40 mL liquid	30 min to 1 hr before first dose; repeat as needed every 4–6 hr
Diphenhydramine (Benadryl)	One or two 25-mg tablets or capsules	1 hr before first dose; repeat as needed every 4–6 hr
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25-mg tablets	1 hr before first dose; repeat if needed in 24 hr
Prescription drugs		
Meclizine hydrochloride (Antivert)	One to two 25-mg tablets	1 hr before first dose; repeat if needed in 24 hr
Promethazine (Phenergan)	One 25-mg tablet or suppository	30 min to 1 hr before first dose; repeat as needed every 8–12 hr
Trimethobenzamide hydrochloride (Tigan)	One 250-mg capsule or 200-mg suppository	1 hr before first dose; repeat as needed every 4–6 hr

^aTiming is relative to the initial dose of emergency contraception.

Source: Reference 39.

interactions compromise the effectiveness of either emergency contraceptive regimen.

Pharmacokinetic drug interactions with ethinyl estradiol may occur via effects on absorption, metabolism, and enterohepatic recycling.²⁹ In theory, drugs that increase gastrointestinal motility, thereby increasing the rate of transit through the gastrointestinal tract, may decrease the absorption of ethinyl estradiol. Vitamin C may increase the bioavailability of ethinyl estradiol by inhibiting its sulfation by enzymes in the gut wall. This could increase the potential for estrogenic adverse effects. Ethinyl estradiol is metabolized by cytochrome P-450 3A4. Drugs that induce cytochrome P-450 3A4 (barbiturates, carbamazepine, efavirenz, ethosuximide, griseofulvin, phenytoin, primidone, rifabutin, rifampin, rifapentine) could decrease plasma ethinyl estradiol concentrations and potentially lead to contraceptive failure.²⁹ Other drugs that can lower ethinyl estradiol concentrations and potentially compromise oral contraceptive efficacy include ritonavir, nelfinavir, and topiramate.²⁶ Some reports suggest that antibiotics may decrease systemic ethinyl estradiol concentrations by killing colonic bacteria and interrupting enterohepatic cycling of estrogens.²⁹

Although levonorgestrel does not appear to undergo extensive hepatic metabolism, inducers of cytochrome P-450 metabolism may also increase its clearance. In a study of 20 women with seizure disorders, phenytoin and carbamazepine decreased the area under the plasma concentration–time curve of levonorgestrel by 40%.⁴² Other hepatic enzyme inducers that may decrease the effectiveness of progestin-only contraceptives include barbiturates and rifampin.³⁰

Special Considerations

Need for Additional Doses After Vomiting

It is unclear whether it is necessary to repeat the dose of emergency contraception if a woman vomits within several hours after taking the tablet(s). Some clinicians believe that nausea and vomiting result from substantial absorption of the estrogen component.⁴ Peak concentrations of ethinyl estradiol and levonorgestrel are achieved within 1.7 hours after a dose of Preven, so repeating the dose may not be necessary if vomiting occurs after this time. Women who vomit within 1 hour of taking a dose of Preven should be advised to contact their health care provider to consider whether to repeat the dose or to take an antiemetic.²⁹ Some clinicians consider vaginal administration of the second dose of the Yuzpe regimen in the event of severe nausea and vomiting; the tablets can be inserted high in the vagina and kept in place with a tampon.¹⁵

A replacement dose of Plan B may be considered when vomiting occurs within 1 hour of administration or when the tablets are observed in the emesis. It should be noted that maximum blood levonorgestrel concentrations are achieved within 1.6 hours of Plan B

administration. Adequate absorption of levonorgestrel may have been achieved by that time.⁴³

Use After 72 Hours

The efficacy of emergency contraceptives when begun more than 72 hours after unprotected intercourse has not been studied. However, it is unlikely that they abruptly become completely ineffective 72 hours after intercourse. Therefore, in some cases, it may be reasonable to begin treatment more than 72 hours after intercourse. Treatment will not harm the fetus if the woman has become pregnant. Alternatively, insertion of an IUD should be considered. The same considerations apply for women who have had multiple recent acts of unprotected intercourse, with some acts occurring more than 72 hours previously. Emergency contraceptives may prevent pregnancy resulting from more recent acts of intercourse, but will not harm the fetus if the woman has already become pregnant.¹⁵

Repeated Use of Emergency Contraceptives

Repeated use of emergency contraception does not pose a health risk to women. However, use of emergency contraception as a primary form of contraception by sexually active women is ill-advised. Although the failure rate of emergency contraception is low based on single use, it would be relatively high on a cumulative basis compared with conventional methods of contraception.^{10,29,30} Also, emergency contraceptives do not offer protection against sexually transmitted diseases. Therefore, women using emergency contraception should be counseled about other readily available contraceptive options (e.g., condoms, spermicides) or referred to their health care provider for consideration of other contraceptive methods.¹⁵

Initiation of Regular Birth Control

Women can begin using oral contraceptive combinations as a regular form of birth control immediately after using emergency contraception.^{15,43} Condoms should be used as a back-up contraceptive during the first week of regular oral contraceptive use. If a woman will use an oral contraceptive combination both for emergency contraception and for routine birth control, there may be an advantage to dispensing Lo/Ovral, Nordette, or Levlen in the familiar “pill pack,” rather than using Preven.¹⁵ The day after taking the second dose of emergency contraception out of the pill pack, the woman can begin taking one tablet a day from the same pack until the pack is finished. High-dose oral contraceptive combinations and triphasic formulations should not be used for this regimen.¹⁵

Barrier contraceptive methods (condoms, diaphragms, spermicides) can be used immediately after emergency contraception.¹⁵ Injectable and implanted hormonal contraceptives can be initiated within 7 days after a woman begins her next menstrual period.¹⁵

The Pharmacist's Role

Pharmacists can play a number of important roles in the provision of emergency contraception. These include counseling patients thoroughly to explain or reinforce key points about emergency contraceptive use and educating patients and prescribers about emergency contraception. In many states, pharmacists are able to enter into collaborative practice agreements that would enable them to prescribe emergency contraception directly to women. At its 2000 Annual Meeting, the American Pharmaceutical Association (APhA) adopted a policy supporting the voluntary involvement of pharmacists, in collaboration with other health care providers, in emergency contraception programs that include patient evaluation, patient education, and direct provision of emergency contraceptive medications.

Patient Counseling Considerations

Points to cover when counseling patients about emergency contraception are listed in Table 5.¹⁵ The importance of taking the first dose as soon as possible and the second dose 12 hours later should be emphasized. However, it may be prudent for some women to delay the first dose for a few hours if taking it immediately might prevent them from administering the second dose on time (e.g., a woman who is a heavy sleeper might not be able to wake up for a second dose timed for 3:00 AM). Written instructions can help to ensure that patients use emergency contraceptives correctly. Sample instructions are provided in Appendix A.

Patients should be reminded that they might experience spotting or a delay in their menstrual cycle after taking emergency contraception. Women who do not menstruate within 21 days after treatment should perform a home pregnancy test or return to their health care provider for evaluation.¹⁵ Emergency contraception may not prevent ectopic pregnancy, a condition that is a medical emergency.⁴ Women who experience symptoms of ectopic pregnancy such as severe lower abdominal pain, spotting after a light or absent menstrual period, and faintness or dizziness should seek medical attention immediately.⁴⁴

Seeking emergency contraception may be a stressful experience for a variety of reasons: for example, fear of pregnancy, sexually transmitted infections, or both; embarrassment about discussing sexual issues; or trauma after a sexual assault. Pharmacists should be as supportive as possible and refrain from making judgmental comments or indicating disapproval (through words, tone of voice, or body language) when counseling women who seek emergency contraception. Pharmacists also should instruct technicians and other pharmacy employees to behave in a nonjudgmental manner during their interactions with the patients.

Ensuring confidentiality is a key issue when counseling women about emergency contraception. Counseling should take place away from the line of patients waiting at most pharmacy counters. A separate room would be ideal, but if that is not available, a more private

area of the pharmacy may suffice. When necessary, pharmacists can use nonspecific language when discussing emergency contraception with patients (e.g., refer to unprotected intercourse as "the event" or "the situation") or they can consider conducting counseling by telephone.¹⁵

If a woman who presents a prescription for an estrogen-progestin preparation does not also present a prescription for an antiemetic, a nonprescription antiemetic such as meclizine can be recommended. Commonly used antiemetics are listed in Table 4. Women should be reminded that most antiemetics can cause sedation, which could interfere with daily activities (e.g., driving) and could make it difficult to awaken if the second dose of emergency contraception is timed for the early morning hours.³⁸

Educating Patients and Health Care Professionals

One of the greatest barriers to the use of emergency contraception is lack of awareness. Even women who know that emergency contraception is available may be unsure about how to obtain it. Considering the short time frame during which therapy can be initiated after unprotected intercourse, health care providers ideally should inform women of the availability of emergency contraception before the need arises.¹⁰ Pharmacists are in a unique position to fill this educational void because they routinely interact with patients obtaining condoms, oral contraceptives, and other forms of contraception. Organizations that provide information about emergency contraception are shown in the Resources box on page 13.

Education about emergency contraception is particularly important for couples who rely on condoms as their primary method of contraception, because emergency contraception can act as a back-up method in the event that a condom should break. The knowledge that a back-up exists may encourage couples to adopt the use of condoms as a method of preventing human immunodeficiency virus (HIV) infection and other sexually transmitted infections.

The Office of Population Research at Princeton University and the Reproductive Health Technologies Project have developed the Emergency Contraception Hotline (1-888-NOT-2-LATE) to inform the public about emergency contraception. This toll-free automated telephone service provides basic information about emergency contraception in English and Spanish. It also provides the caller with the names and phone numbers of the five closest health care professionals who prescribe or provide emergency contraception. Pharmacists can help women become more knowledgeable about emergency contraception by making them aware of the hot line and displaying materials developed in support of the service. Wallet cards and posters publicizing the hot line can be obtained by calling the hot line directly or contacting the Reproductive Health Technologies Project (see Resources box).¹⁴

All pharmacy employees should be aware of key issues involving emergency contraception, such as the need to begin therapy as

Pharmacist Prescribing of Emergency Contraception: The Washington State Experience

by Don Downing, RPh, Pharmaceutical Care Coordinator, University of Washington/Washington State University/Washington State Pharmacists Association

From July 1997 to July 1999, the Washington State Pharmacists Association (WSPA), in partnership with the Program for Appropriate Technology in Health (PATH, a multinational nonprofit organization), the Washington State Board of Pharmacy (WSBP), the University of Washington Department of Pharmacy, and Elgin DDB Seattle (a public relations company), conducted a pilot project that broke new ground in U.S. reproductive health care access. The Emergency Contraception Collaborative Agreement Pilot Project, funded by the David and Lucille Packard Foundation (a Seattle-area private foundation that provides grants to nonprofit organizations), investigated the feasibility of having pharmacists prescribe emergency contraception directly to women in need. The goal was to increase women's access to emergency contraception. At the time the project was conceived, emergency contraception was little known and little used, even though it had been available for more than 25 years.

Project Planning

The project originated at a 1997 meeting of the Northwest Emergency Contraception Coalition (NECC). PATH, Planned Parenthood of Western Washington, and other public health agencies formed NECC in 1996 with the goal of raising awareness of, and improving access to, emergency contraception nationwide and worldwide. During that meeting, a pharmacist in attendance pointed out that collaborative practice legislation in Washington State put pharmacists in an ideal position to help further NECC's aims. Under collaborative drug therapy agreements for providing emergency contraception services (see sidebar "Collaborative Practice Legislation and Emergency Contraception Services"), pharmacists would have the authority to prescribe and dispense emergency contraception; a woman would be able to go directly to a participating pharmacy to obtain the medication and counseling without having to visit or even contact her usual prescriber.

The partnership among PATH, WSPA, WSBP, and Elgin DDB was formed soon after this meeting. The PATH staff took the idea for the pilot project to the David and Lucille Packard Foundation, reasoning that if the project successfully improved access to emergency contraception services in the foundation's "own backyard," the idea of pharmacist prescribing might be expanded to other states. The WSPA board of directors discussed the proposed pilot project at its next meeting but did not embrace the project immediately. After reviewing data showing that almost half of the 56,000 unintended pregnancies in Washington State resulted in induced abortions, and

that oral emergency contraceptives had the same mechanism of action as the oral contraceptives dispensed daily by pharmacists, the WSPA board decided to move forward.

One of the specific objectives established for the pilot project was to conduct a 3-month to 6-month public awareness media campaign to inform women aged 18 to 34 years of the availability of emergency contraceptives through pharmacies. Elgin DDB was instrumental in developing and implementing this campaign, which included radio and print advertisements. Letters were written to area health care leaders, asking them to participate on a project advisory committee that would guide project development and help to communicate the project's objectives to the public, the media, and public and private agencies. The committee that was assembled included distinguished representatives of the Washington State legislatures, state and local health departments, the Department of Health and Human Services, the King County Academy of Family Practice Physicians, Blue Shield, the Northwest Women's Law Center, and a local independent pharmacy. Five of the nine committee members were physicians, which proved to be especially helpful in gaining the medical community's support of the project. In October 1998, the Washington State Medical Association House of Delegates adopted a resolution in support of the provision of emergency contraception by pharmacists in Washington State.

Preparing Pharmacists

To be successful, the pilot project needed a critical mass of pharmacists providing emergency contraception services in the project area (the counties in Washington State that lie next to the Interstate 5 corridor along Puget Sound). Therefore, before the media campaign began, we made it a priority to provide pharmacists with emergency contraception information and training. WSPA members were recruited for the project via notices in the *Washington Pharmacist* and *Rx Et Cetera* newsletters. To help WSPA members make an informed decision about participating in the project, University of Washington School of Pharmacy faculty member Jackie Gardner prepared an article titled "Emergency Contraceptive Pills: Safe & Effective But Not Widely Used" that was published in the *Washington Pharmacist*.

A low-cost training program was offered to interested pharmacists on weekends and evenings. Various training formats were tried, but we finally settled on a 3-hour live program. The training encompassed collaborative drug therapy agreements, issues dealing with

Collaborative Practice Legislation and Emergency Contraception Services

Since 1979, the Washington State Pharmacy Practice Act has given pharmacists authorization for *"the initiating or modifying of drug therapy in accordance with written guidelines or protocols... approved... by a practitioner authorized to prescribe drugs"* (RCW 18.64.011). The final regulations were set down in 1981 by the Board of Pharmacy and required that there be defined guidelines, quality assurance, documentation, and scheduled protocol reviews agreed upon by the pharmacist and prescriber before the collaborative protocol and agreement are accepted by the Board of Pharmacy (WAC 264-863-109). The licensed prescriber has the primary obligation to authorize and monitor the pharmacist's conduct under the collaborative agreement, while the Board of Pharmacy determines that the protocols are prepared properly and that the pharmacists are practicing within the guidelines outlined in the protocol. Collaborative drug therapy agreements have been used successfully in Washington State in many settings for programs such as immunizations, anticoagulation management, smoking cessation, prescription refills, pain management, and disease management.

Under collaborative agreements for emergency contraception services, all pharmacists begin by determining patient eligibility for care (e.g., the patient is not pregnant, the patient has had unprotected intercourse within the past 72 hours). If the patient is a candidate for therapy, the pharmacist and patient review and discuss the limitations of emergency contraceptives, potential adverse effects, and the importance of treatment adherence. The pharmacist and patient also review and sign a standard consent form. The form doubles as documentation of the encounter; the pharmacist often writes additional "SOAP note" information on the back. The signed form and the pharmacy's primary dispensing computer information become the patient's emergency contraception chart, and the information is filed securely in the pharmacy.

As part of the emergency contraception services, pharmacists determine whether patients should be referred immediately to other health care professionals for ongoing contraception (e.g., a prescription for oral contraceptives or a diaphragm) or to be evaluated and treated for sexually transmitted infections. Patients without a primary care provider are given names, phone numbers, and business cards of local physicians or clinics where they can be seen. Depending on the circumstances, pharmacists also may refer patients to Child Protective Services or domestic violence or rape counseling resources.

patient care, dispensing and therapeutic information, public relations, and insurance. Special emphasis was placed on appropriate patient referral, quality assurance, the need for private counseling areas, and child and adult abuse resources in the community. A training and operations manual was developed using published literature and PATH and Elgin DDB resources; it included local patient provider lists, case studies, and reimbursement resources provided by Washington State Medicaid. Pharmacists' competency to provide emergency contraception services was evaluated using individual and group case-study analysis and discussion. (This training program has since been used in emergency contraception programs in other states and countries.)

Pharmacists who attended the training programs also received a collaborative drug therapy agreement template for emergency contraception services that had been designed by a WSBP consultant (and collaborative agreement specialist). (*Editor's note: This template is provided as Appendix B of the Special Report.*) As a final step toward building a critical mass of pharmacy providers, the WSBP instituted a fast-track review of emergency contraception collaborative agreements that adhered to this template. To help link pharmacists with willing collaborating prescribers, we sent letters to the state and local county health departments as well as local Planned Parenthood affiliates, asking for the names of physicians and nurse practitioners who might be interested in participating in the pilot project. The response was overwhelming, with willing collaborators numbering in the hundreds. Each pharmacist received a list of physicians and nurse practitioners in his or her area, which simplified the process of contacting and entering into an agreement with an authorized prescriber.

In anticipation of possible opposition to the project, information concerning the role of pharmacists in prescribing emergency contraception was distributed to various groups (e.g., state and national right-to-life organizations). We discovered that most groups did not make an official stand against the use of emergency contraception. Many stated that because pharmacy-based emergency contraception services would increase accessibility to this treatment option and most likely decrease the number of abortions performed in the state, they would not oppose the project.

One question that arose during the project planning stages was whether pharmacists would be able to prescribe emergency contraception to minors. In Washington, state laws authorize minors (no age limit) to consent to contraceptive and family planning services (Initiative 120, RCW 9.02.100); hence, no parental consent or notification is required for contraceptive services. We teach pharmacists that minors are assured the same confidentiality as all other patients. As part of the project training, pharmacists were taught how to facilitate parent-minor discussions regarding the child's contraceptive use and sexual activity. At times during the project, pharmacists have found themselves being the catalyst for the first such discussions that the parent and the child have had.

Project Outcomes

The collaborative efforts and commitments of all involved parties resulted in the achievement of all project goals by the end of the first year of the 2-year pilot period. Some key objectives, as stated in the original proposal, are listed below, followed by end-of-project achievements.

- 1. Inform at least 500 community pharmacists in the Puget Sound area of Washington State about collaborative drug therapy agreements for emergency contraception.** By the end of the project, at least 4000 pharmacists in Washington State had received information about the pilot project and been given the opportunity to provide emergency contraception services through collaborative agreements. This was accomplished via training programs, newsletters, faxes, magazine articles, and presentations to local and state pharmacy groups.
- 2. Deliver tools and training for emergency contraception services to at least 250 pharmacists.** At the end of the project, a total of 819 practicing pharmacists and 298 pharmacy students had completed the WSPA emergency contraception training. Funding was provided initially for three 3-hour training

programs; however, the overwhelming demand from pharmacists for additional training opportunities resulted in more than 50 training programs being provided during the project. These training sessions were self-funded by charging a slightly higher fee for participants. Training programs currently are offered to students and practitioners at least once a year on the campuses of both Washington State pharmacy schools. Pharmacy staff members (including technicians and assistants) as well as local nurses and physicians are invited to all training programs.

Written patient information on emergency contraception has been made available by pharmacists in 13 languages. Use of the standard consent form (which also serves as the primary patient care chart and quality assurance tool) by all pharmacist providers has yielded consistent patient information and documentation records.

- 3. Develop systems to facilitate the establishment of 100 collaborative agreements for emergency contraception services.** At the end of the pilot project period in June 1999, 143 collaborative agreements were on file with the WSBP, representing 33% of all collaborative agreements in the state. The number of pharmacies offering emergency contra-

Lessons Learned From the Emergency Contraception Collaborative Agreement Pilot Project

- Key groups—including pharmacy, medicine, and public health communities—within the state must be highly motivated to expand emergency contraception access through pharmacies, and collaboration and substantial support of these key groups are essential to success.
- Awareness-raising strategies should include not only an initial intensive campaign, but also subsequent sustainable, localized, and low-level marketing efforts—possibly pharmacy-based.
- After an initial intensive media campaign, word of mouth appears to grow and contribute to expanding awareness.
- Coverage by public and private sector insurers is critical to broadly expanding emergency contraception access, and these third party payers must be brought into the process early on. Washington State Medicaid program was quick to see the importance of coverage for this service, but private sector insurers have been reluctant to cover any contraceptive services.
- Even if insurers currently pay for emergency contraceptive services, there must be a clarified emergency contraception services payment policy if pharmacists are to be paid for their counseling services. Otherwise, compensation collected by pharmacists for their emergency contraception interventions, counseling, and referrals may be deemed in violation of current insurer-pharmacy contracts.
- Fear of backlash is more inhibiting than the impact of actual negative community reaction. Some pharmacists and pharmacy corporations did not initially become involved in this project for fear of boycotts and loss of business. Although a few letters were written by people opposed to this service, no boycotts have occurred. A number of pharmacists were told by new customers that they gained their new business because they offered this new service choice.
- Education of pharmacists is critical. Some pharmacists who were reluctant to provide emergency contraception services changed their minds after attending a training program. They indicated that they initially had misunderstood the mechanism of action of emergency contraceptives.

ception services continues to increase; services are available at outlets of five pharmacy chains as well as independent pharmacies.

Data taken from client surveys and pharmacy chart reviews indicate that the primary goal of the project—to increase access to emergency contraception—was met successfully. By the end of the pilot project, pharmacists had written and filled 11,969 prescriptions for emergency contraception. A review of 991 pharmacy records revealed that 70% of women received emergency contraception services from a pharmacy within 1 day of unprotected intercourse. Of these women, 24.1% received emergency contraception services on the same day as unprotected intercourse.

Most women heard about pharmacy-based emergency contraception services through the media, another 22.4% heard through a friend, and 19.3% heard about pharmacy emergency contraception services from their physician or clinic. Most respondents (76.4%) went directly to a pharmacy for emergency contraception services (rather than consulting a physician or clinic) because of convenience. More than 40% of the women received emergency contraception services from pharmacies during evenings, weekends, or holidays, highlighting the unique service that pharmacists can provide.

It is noteworthy that more than 11,969 patients actually were counseled by pharmacists, because not all patient encounters resulted in a prescription for emergency contraception pills. There have been a number of instances in which a patient thought that she had not used contraception correctly (e.g., took her oral contraceptives an hour later than usual) or had erroneously thought that she could become pregnant (e.g., swam in the same swimming pool as men).

Other interesting and important data from the project include the following:

- The mean age of women who sought emergency contraception services was 24.5 years. Only 13% were under 18 years of age, and 8.7% were older than 35 years of age.
- The need for emergency contraception services was attributed to contraceptive failure by nearly 60% of the respondents.

- 20% of the respondents reported that they went to a pharmacist because their regular physician's office was closed.
- 7% of the women reported that their regular physician or clinic didn't prescribe emergency contraception.
- 14.8% of the women reported that they had no regular physician or clinic.

In November 1999, the Washington State Department of Health released its 1998 statistics (the first year of pharmacist-provided emergency contraception services) showing that the state's abortion rate had dropped more steeply than at any time in the past decade. The report also noted that the teen pregnancy rate had declined to its lowest level in 20 years. The Department of Health noted the connection between these declines and the increased use of contraception, particularly emergency contraception. This is the first statistical indication of what may well be an emerging trend, and increased access to emergency contraception services through pharmacies can be seen as one contributing factor.

The Future

While the Emergency Contraception Collaborative Agreement Pilot Project has been a success, it is only the beginning of such services in Washington State. Patient encounters for emergency contraception services have continued to climb since the pilot project ended. More pharmacists are deciding to become involved in this service, and access to this important contraceptive service in Washington State continues to increase. We have just received federal funding from the Temporary Aid to Needy Families program to expand the program to the more rural areas of Washington State. The highest unintended birth rates and percentage of births paid by Medicaid in Washington State are all in rural counties; pharmacists are often the only permanent health care providers in those areas and are in an excellent position to provide contraceptive education, counseling, and referral services. We look forward to educating many more pharmacists, nurses, and physicians about this service.

soon as possible within 72 hours after unprotected intercourse. Clerks and technicians often are a patient's first point of contact in a pharmacy, and it is important that they be well informed and able to assist women seeking information.¹⁵

Unfortunately, many health care professionals (including pharmacists) are unaware of or ill informed about emergency contraception. A number of resources are available to help pharmacists teach their colleagues about emergency contraception (see Resources box). Well-planned educational programs can help to establish emergency contraceptive services even in relatively conservative organizations, as evidenced by a successful demonstration and evaluation project conducted at Kaiser Permanente Southern California in conjunction with the Pacific Institute of Women's Health.⁴⁵ The Washington State Pharmacists Association and the Program for Appropriate Health Technology routinely provide pharmacist training on emergency contraception in a number of states (see the discussion in the next section and the accompanying article "Pharmacist Prescribing of Emergency Contraception: The Washington State Experience" on pages i–iv).

Prescribing Emergency Contraceptives Under Collaborative Practice Agreements

Pharmacists can assume an active role in providing women with timely emergency contraception by entering into collaborative practice agreements that enable them to prescribe and dispense emergency contraception. A collaborative practice agreement is a voluntary relationship between a pharmacist and an authorized prescriber that enables the pharmacist to manage a patient's drug therapy within the limits of an agreed-upon treatment protocol. Legislation authorizing collaborative practice agreements exists in at least 25 states; pharmacists should contact their state board of pharmacy to determine whether they are permitted to establish such relationships with independent prescribers in their state.⁴⁶ The terms of such agreements vary widely; some limit the pharmacist's activities to monitoring and making prespecified adjustments in drug therapy, while other broad agreements enable pharmacists to initiate drug therapy (the latter are the types of agreements used in pharmacy-based immunization programs).

Collaborative practice agreements that enable pharmacists to prescribe and dispense emergency contraception make particular sense because pharmacies usually offer convenient business hours and locations.^{47,48} Pharmacies often are open when other health care providers are not available (e.g., on evenings, weekends, and holidays)—times when the need for emergency contraception might be most likely to arise. For many women, especially younger women who do not have a regular health care provider, obtaining emergency contraception directly from a pharmacist would circumvent the long wait often experienced by patients (especially new clients) seeking to schedule an appointment with a physician. All of these factors help

Table 5.

Important Points for Counseling Patients About Emergency Contraceptives

- Make certain that the patient does not want to get pregnant.
- Explain how to take emergency contraceptives correctly.
- Describe potential adverse effects and how to manage them.
- Emphasize that emergency contraception is for emergency use only.
- Recommend that another form of contraception be used if a woman is sexually active again. The risk of pregnancy may be high soon after treatment if emergency contraception has delayed ovulation, and emergency contraception does not protect against pregnancy after treatment.
- Explain that emergency contraception does not protect against sexually transmitted infections.
- Tell the patient that her next period may be a few days early or late.
- Explain that emergency contraception can fail. If the woman's period does not come within 21 days after treatment, she should perform a home pregnancy test or contact her health care provider.
- Provide written instructions.
- Encourage the patient to call if she has any questions.
- Make referrals to Child Protective Services, domestic violence or rape relief resources, or other health care providers as needed for ongoing contraception, IUD insertion, or sexually transmitted infection evaluation and treatment.

Source: Reference 15 and personal communication, Don Downing, Washington State Pharmacists Association, February 5, 2000.

to ensure that women obtain emergency contraception as soon as possible after unprotected intercourse, thereby increasing the likelihood that it will be effective.^{22,37}

The inability of existing systems to consistently provide timely access to emergency contraception was illustrated by a recent quality assurance study that evaluated the referral services of the Emergency Contraception Hotline and the Emergency Contraception Web site.⁴⁶ In this study, investigators posed as women seeking emergency contraception because a condom had broken the night before. During regular working hours, they called 200 randomly selected medical providers listed by the hot line. (Pharmacists who provide emergency contraception services were not included in the study.) Only 76% of attempts led to an appointment or prescription for emergency contraception within 72 hours. Almost 20% of the time that calls were successful, the caller was asked to wait at least 24 hours for an appointment or a walk-in visit. In addition, some providers required a pregnancy test or pelvic examination before prescribing emergency contraception. These diagnostic tests are medically unnecessary, time-consuming, and costly.⁴⁶

An example of an emergency contraception access program built on collaborative practice agreements exists in Washington

State. In 1997, the Washington State Pharmacists Association, the Washington State Board of Pharmacy, and several other collaborating organizations developed the Emergency Contraception Collaborative Agreement Pilot Project.^{47,48} The collaborative practice agreements used in this program allow pharmacists to counsel women about emergency contraception and to prescribe emergency contraceptives either in response to an immediate need or for women to have on hand for future use (Appendix B).⁴⁹ To participate in the program, pharmacists complete a training program and then, with the sponsorship of an independent prescriber, file a collaborative drug therapy agreement with the Washington State Board of Pharmacy. The pharmacist documents each encounter in a patient profile and periodically reviews these documents with the sponsoring independent prescriber. Charges for the service vary by pharmacy but average \$35 to \$40.⁴⁸

A media campaign at the beginning of the project helped to raise community awareness of the availability of emergency contraception services at local pharmacies. In addition, women from Idaho, Oregon, and Washington who call the Emergency Contraception Hotline (1-888-NOT-2-LATE) are given the names and phone numbers of the five closest pharmacies in Washington State whose pharmacists are authorized to prescribe emergency contraception (personal communication, Don Downing, Washington State Pharmacists Association, February 5, 2000).

This project clearly has been successful. Within 4 months of the program's launch, more than 100 pharmacies were participating in the project, and more than 500 pharmacists had completed the required training.^{48,50} Data from the first 4 months of program operation indicated that more than 2700 prescriptions for emergency contraceptives were written and filled by pharmacists.^{47,48,50} One participating pharmacy chain reported filling a total of 141 prescriptions in the month following the launch, compared with 7 known prescriptions during the 2 months preceding the launch.⁴⁸ During the first 4 months, it is estimated that the program prevented 207 unintended pregnancies and 103 induced abortions.⁴⁷ (For more current statistics about the Washington State project, see the accompanying article "Pharmacist Prescribing of Emergency Contraception: The Washington State Experience" on pages i-iv.)

A survey of women who filled prescriptions through the program during its first 2 months of operation found that half did so after normal business hours (i.e., on a weekend or after 6:00 PM on a weeknight).⁴⁸ Slightly more than half had experienced contraceptive failures. Approximately 40% of the women surveyed said that they would have taken no action to prevent pregnancy if they had been unable to receive emergency contraception through a pharmacy.^{47,50}

Conscience Clauses

Some people believe that all oral contraceptives (including those used as emergency contraceptives) are abortifacients, because they believe that pregnancy begins with the fertilization of an egg

rather than with implantation of the blastocyst in the endometrium.⁵¹ This creates a dilemma for pharmacists whose personal moral or religious beliefs about oral contraceptives conflict with their professional responsibility to serve the needs of the patient. Employment policies, otherwise known as "conscience clauses," are being developed to deal with these sorts of issues (dispensing medications to be used for executions by lethal injection is another example). These policies call for (1) pharmacists to notify their employers of a conscientious objection at the earliest opportunity and (2) employers to provide reasonable accommodation of that employee pharmacist's belief as well as an alternative mechanism for filling the patient's prescription.⁵² In 1998, APhA adopted a policy that recognizes the pharmacist's right to exercise conscientious refusal and also supports the establishment of systems that ensure patient access to legally prescribed medications.⁵³

In the case of emergency contraceptives, conscience clauses may not completely resolve the conflict if a referral from one pharmacy to another results in a substantial delay beyond the 72-hour window during which the medications are known to be effective. Such a delay could create an insurmountable barrier to obtaining emergency contraceptives for women who live in rural areas where there may be few pharmacies.

Summary

With FDA approval of the dedicated products Preven and Plan B, more than 5 million women are expected to use emergency contraceptives each year. In light of this increasing use, pharmacists need to become knowledgeable about women's options for emergency contraception, including the advantages and disadvantages of each choice.

The Yuzpe regimen of emergency contraception is readily available as Preven or through the off-label use of oral estrogen-progestin contraceptive combinations. The regimen frequently causes nausea and vomiting; antiemetics usually are provided to prevent this. A regimen that uses levonorgestrel alone (available as the dedicated product Plan B or by administering 20 Ovrette tablets per dose) may become the emergency contraceptive regimen of choice because it appears to be more effective and is better tolerated than the Yuzpe regimen. A copper-containing IUD also may be inserted for emergency contraceptive purposes, but this can be done only by a qualified health care practitioner.

Pharmacists can help overcome barriers to the use of emergency contraception through the education of their patients and other health professionals. They should develop effective counseling skills and become sensitive to the emotional turmoil that women may be experiencing when they seek emergency contraception. Pharmacists also may be able to participate in collaborative practice agreements in which they write and dispense prescriptions for emergency contraception, allowing women immediate access to this "second chance" to prevent pregnancy.

Resources

Association of Reproductive Health Professionals

2401 Pennsylvania Avenue NW, Suite 350
Washington, DC 20037-1718
Phone: (202) 466-3825
Fax: (202) 466-3826

Web site: <http://www.arhp.org/ec/>

- This organization has created a "train-the-trainer" educational program that health professionals can use to teach other health professionals about emergency contraception. Slide sets and teaching points on emergency contraception can be downloaded from Web site. They also can be obtained by calling Liz Callihan at (877) 320-8995.

Center for Reproductive Law and Policy

120 Wall Street
New York, NY 10005
Phone: (212) 514-5534
Fax: (212) 514-5538
E-mail: info@crfp.org

Web site: <http://www.crlp.org/>

- Source of a 1997 publication entitled *Emergency Contraceptive Pills: Common Legal Questions about Prescribing, Dispensing, Repackaging and Advertising*.

Gynetics, Inc.

P.O. Box 8509
Somerville, NJ 08876
Phone: (908) 359-2429

Web site: <http://www.preven.com/>

- The Web site provides patient- and health care provider-oriented information about Preven.

Office of Population Research

Princeton University
21 Prospect Avenue
Princeton, NJ 08544
Phone: (609) 258-4870
Fax: (609) 258-1039

Web site: <http://ec.princeton.edu>

- This organization's Web site provides comprehensive information about emergency contraception in English and Spanish for both health professionals and consumers. It also maintains an on-line directory of health care providers who prescribe emergency contraception.

Planned Parenthood Federation of America

810 Seventh Avenue
New York, NY 10019
Phone: (212) 541-7800 or (800) 669-0156
Fax: (212) 245-1845

E-mail: communications@ppfa.org

Web site: <http://www.plannedparenthood.org/>

- The Web site provides information for health professionals and the public on all forms of contraception and abortion, sexually transmitted infections, and other women's health issues.
- Planned Parenthood Federation of America has a variety of patient education materials on emergency contraception including brochures, wallet cards, and a handbook.

- Women can call 1-800-230-PLAN or go to the organization's Web site to locate the nearest Planned Parenthood clinic that provides emergency contraception.

Program for Appropriate Technology in Health (PATH)

4 Nickerson Street
Seattle, WA 98109-1699
Phone: (206) 285-3500
Fax: (206) 285-6619

E-mail: info@path.org

Web site: <http://www.path.org/>

- Source of (1) *Emergency Contraception: Client Materials for Diverse Audiences*, 2nd edition, and (2) *Emergency Contraception: Resources for Providers* by Wells E, Crook B, and Muller N. (These publications are also available from Planned Parenthood.)
- A set of "tools" that was developed as part of a notebook for a workshop in May of 1999 intended to help states develop and implement a project similar to the pharmacist prescribing initiative in Washington State is available on the PATH Web site at http://www.path.org/resources/ec_tools.htm.
- For information about pharmacist collaborative therapy agreements, contact Jane Hutchings (jh@path.org).

Reproductive Health Technologies Project (Emergency Contraception Hotline)

P.O. Box 33344
Washington, DC 20033
Phone: (202) 530-2900
Fax: (202) 530-2901

Hot line: (888) NOT-2-LATE (888-668-2528)

- Automated patient-oriented service provides information about emergency contraception and referral to local health care providers 24 hours a day. Information is in English and Spanish.
- A variety of patient education materials on emergency contraception are available, including brochures and wallet cards.

Washington State Pharmacists Association

1501 Taylor Avenue, SW
Renton, WA 98055
Phone: (425) 228-7171
Fax: (425) 277-3897

Web site: <http://www.pharmcare.org>

- For information about pharmacist collaborative therapy agreements, contact Don Downing (dondown@u.washington.edu).

Women's Capital Corporation

P.O. Box 5026
Bellevue, WA 98009
Phone: (800) 330-1271
Fax: (425) 739-2036

Web site: <http://www.gotoplanb.com/>

- Web site provides patient- and health care provider-oriented information about Plan B.

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How to Use Emergency Contraceptive Pills

If you have had sex without birth control or your birth control method failed within the past 3 days, you can use emergency contraceptive pills (ECPs) to reduce your risk of pregnancy. If you had sex without birth control more than 3 days ago, you may be able to have an IUD inserted to prevent pregnancy (contact your health care provider as soon as possible).

Types of Pills

Any of the birth control pills listed below can be used as ECPs. Use only the type of pill your health care provider prescribed for you. Use only one type of pill.

If you are taking:	Number of pills to swallow as soon as possible (first dose)	Number of pills to swallow 12 hours later (second dose)
Dedicated products		
Preven	2 blue pills	2 blue pills
Plan B	1 white pill	1 white pill
Oral contraceptive pills		
Alesse	5 pink pills	5 pink pills
Levlen	4 light-orange pills	4 light-orange pills
Levite	5 pink pills	5 pink pills
Levora	4 white pills	4 white pills
Lo/Ovral	4 white pills	4 white pills
Ovral	2 white pills	2 white pills
Ovrette	20 yellow pills	20 yellow pills
Nordette	4 light-orange pills	4 light-orange pills
Tri-Levlen	4 yellow pills	4 yellow pills
Triphasil	4 yellow pills	4 yellow pills
Trivora	4 pink pills	4 pink pills

Timing of Doses

- If you are using an anti-nausea medication like Dramamine II or Benadryl, take the first dose 1 hour **before** you take the first dose of ECPs. Repeat according to labeled instructions.
- Take the first dose of ECPs *as soon as possible within 72 hours (3 days)* after having unprotected sex. If possible, time the first dose so that the timing of the second dose will be convenient.
- Take the second dose of ECPs **12 hours after taking the first dose**.
- **Important: Do not take any extra ECPs.** Taking more pills will not make the method work better and will increase the chance you will feel sick to your stomach.

What to Expect

- Some women who use ECPs feel sick to their stomach, and a few women vomit. Some women also feel dizzy or tired or have tender breasts. These side effects are not serious and usually stop in a day or so. If you vomit within 2 hours of taking the pills, call your provider for instructions.
- Your period may come on time or be a few days early or late.
- **Important:** ECPs are not 100% effective. If your period does not start within 3 weeks after taking ECPs, there is a chance that you may be pregnant. See your health care provider or do a home pregnancy test.

Preventing Pregnancy in the Future

- ECPs do not protect you against pregnancy **after** treatment. Use condoms, spermicides, or a diaphragm after using ECPs until your next period starts. You can switch to a different birth control method then.
- ECPs are meant for emergency protection. ECPs are not as effective as other forms of regular birth control. Talk to your health care provider about other regular birth control methods you can use to prevent pregnancy in the future. Protect yourself against AIDS and other sexually transmitted diseases as well as pregnancy—use condoms every time you have sex if you think you may be at risk.

Source: Adapted from reference 2.

Emergency Contraception Collaborative Practice Agreement Protocol

As a licensed health care provider authorized to prescribe medications in the State of _____, I authorize _____, R.Ph., and other pharmacists employed at _____ Pharmacy to prescribe emergency contraceptive pills (ECPs) according to the protocol that follows. The protocol provides written guidelines for initiating drug therapy in accordance with the laws and regulations of the State of _____.

Purpose: To provide access to emergency medication within the required time frame and to ensure the patient receives adequate information to successfully complete therapy.

Procedure: When the patient requests ECPs, the pharmacist will assess the need for treatment and/or referral for contraceptive care. The pharmacist will determine the following:

- The date of the patient's last menstrual period to rule out established pregnancy;
- That the elapsed time since unprotected intercourse is less than 72 hours;
- Whether the patient has been a victim of sexual assault; and
- The age of the patient.

The pharmacist will refer the patient to see a physician or family planning clinic provider if established pregnancy cannot be ruled out or if the elapsed time is more than 72 hours.

If there is a concern that the patient may have contracted a sexually transmitted disease through unprotected sex, and/or the patient indicates that she has been sexually assaulted, the pharmacist will initiate appropriate referral while providing ECPs. When the patient is a minor and sexual assault or abuse is suspected, the pharmacist will report or cause a report to be made to Child Protective Services.

The pharmacist may also prescribe and dispense a course of ECPs to a patient who is at risk in advance of the need for emergency contraception. In addition the pharmacist will counsel the patient on available options for regular contraceptive methods or offer to refer for additional contraceptive services. While ECPs can be used repeatedly without serious health risks, patients who request ECPs repeatedly will be referred to a physician or family planning clinic provider for use of a regular contraceptive method.

The pharmacist will dispense only the number of ECPs required for one of the regimens listed in [Table 1 of this Special Report]. Along with the medication, patients will be provided with information concerning dosing, potential adverse effects, and follow-up contraceptive care. For patients at risk for vomiting, the pharmacist may provide one of the antiemetics shown in [Table 4 of this Special Report] to be taken before ECPs.

Each prescription authorized by the pharmacist will be documented in a patient profile as required by law. A quarterly report of ECP prescribing will be provided to the licensed health care provider(s) authorizing this agreement.

The pharmacist(s) who participate in the protocol must have completed training covering the procedures listed above, the management of the sensitive communications often encountered in emergency contraception, service to minors, and a crisis plan if the pharmacy operations are disrupted by individuals opposing emergency contraception. Further, the pharmacists agree to participate in the Emergency Contraception Hotline and provide data without patient identifiers to the Emergency Contraception Project.

The prescriptive authority is granted for a period of 2 years from the date of approval unless rescinded in writing earlier by either the authorizing prescriber or the pharmacist. On a quarterly basis, the authorizing prescriber and the pharmacist will perform a quality assurance review of the prescribing decisions according to mutually acceptable criteria.

Date _____

Signed:

Authorizing prescriber _____ License # _____

Authorized pharmacist _____ License # _____

Source: Reference 39.

C.E. Assessment Questions

Instructions: For each question, circle the letter on the "C.E. Credit" page at the end of this publication that corresponds to the correct answer below. **Please review all of your answers to be sure you have circled the intended response.** There is only one correct answer to each question.

1. **Pregnancy is most likely to occur if a woman engages in unprotected sexual intercourse:**

- One week after ovulation.
- During the 6 days leading up to ovulation.
- Very early in the follicular phase of the menstrual cycle.
- During menses.
- None of the above answers is correct.

2. **The original Yuzpe regimen of emergency contraception consisted of:**

- Two doses of danazol 800 mg taken 12 hours apart.
- Two doses of ethinyl estradiol 100 µg and DL-norgestrel 0.1 mg taken 12 hours apart.
- Two doses of ethinyl estradiol 500 µg and DL-norgestrel 0.5 mg taken 12 hours apart.
- Two doses of levonorgestrel 0.75 mg taken 12 hours apart.
- None of the above answers is correct.

3. **To be effective, the first dose of an oral emergency contraceptive regimen should be taken no later than:**

- 5 days after unprotected sexual intercourse.
- 72 hours after unprotected sexual intercourse.
- 48 hours after unprotected sexual intercourse.
- 24 hours after unprotected sexual intercourse.
- 12 hours after unprotected sexual intercourse.

4. **A copper-releasing IUD can be inserted as emergency contraception:**

- Up to 3 days after unprotected sexual intercourse.
- Up to 4 days after unprotected sexual intercourse.
- Up to 5 days after unprotected sexual intercourse.
- Up to 10 days after unprotected sexual intercourse.
- Up to 2 weeks after unprotected sexual intercourse.

5. **If 100 women used the Yuzpe regimen of emergency contraception after a single act of unprotected intercourse, the expected number of pregnancies would be reduced from:**

- 20 to 10.
- 4 to 2.
- 9 to 5.
- 8 to 2.
- 8 to 4.

6. **If 100 women used a regimen of levonorgestrel alone for emergency contraception after a single act of unprotected intercourse, the expected number of pregnancies would be reduced from:**

- 8 to 1.
- 8 to 2.
- 20 to 10.
- 8 to 4.
- 4 to 2.

7. **Which of the following is an indication for use of emergency contraception?**

- A condom slipped, broke, or leaked.
- A couple had sexual intercourse without using any contraception.
- A woman missed one or more progestin-only contraceptive tablets.
- A woman is more than 2 weeks late for a contraceptive injection.
- All of the above answers are correct.

8. **The typical woman seeking emergency contraception:**

- Is more than 35 years of age.
- Has had no previous sexual encounters.
- Already has several children.
- Has experienced known or suspected failure of a primary method of contraception.
- Answers a and c both are correct.

9. Which of the following statements about starting oral contraceptives after the use of emergency contraceptives is true?

- a. Oral contraceptive combinations can be given starting on the first day after the last dose of emergency contraception.
- b. The use of a back-up contraceptive method, such as condoms, is not necessary after a woman takes her first dose of the oral contraceptive combination.
- c. Oral contraceptive combinations must never be used in the same cycle as emergency contraceptives.
- d. Triphasic pill formulations are the preferred oral contraceptives for this use.
- e. High-dose pill formulations are the preferred oral contraceptives for this use.

10. A recent study showed that giving women a supply of emergency contraceptives ahead of time to use as needed in the future:

- a. Was safe.
- b. Did not change the way they used other contraceptives.
- c. Did not lead to excessive reliance on emergency contraception.
- d. Led to correct use of the regimen when women had written instructions to follow.
- e. All of the above answers are correct.

11. Which of the following statements about the risk of nausea and vomiting with emergency contraceptives is true?

- a. Approximately 50% of women taking the Yuzpe regimen (Preven) become nauseated and about 20% of them may vomit.
- b. Approximately 23% of women taking levonorgestrel alone (Plan B) become nauseated and about 6% of them may vomit.
- c. Giving an antiemetic 1 hour before each dose of the Yuzpe regimen may decrease the risk of nausea or vomiting.
- d. The routine administration of an antiemetic is not recommended before administration of Plan B.
- e. All of the above answers are correct.

12. Which of the following statements about drug interactions with ethinyl estradiol is true?

- a. Vitamin C may decrease the bioavailability of ethinyl estradiol.
- b. Plasma ethinyl estradiol levels may be increased by ritonavir, nelfinavir, and topiramate.
- c. Inducers of cytochrome P-450 such as rifampin and carbamazepine could induce the metabolism of ethinyl estradiol.
- d. Some antibiotics may increase systemic levels of ethinyl estradiol by killing colonic bacteria and interrupting enterohepatic recycling of the estrogen.
- e. All of the above answers are correct.

13. Women should be counseled not to rely on emergency contraception as their primary method of birth control because:

- a. It has a high rate of serious adverse effects.
- b. It is very expensive compared with other birth control methods.
- c. It is less effective than other birth control methods when used on a regular basis and does not protect against sexually transmitted diseases.
- d. Emergency contraceptives are not available in the United States.
- e. All of the above answers are true.

14. A woman should use a home pregnancy test or contact her health care provider if she does not get her menstrual period:

- a. Within 5 days after using emergency contraceptives.
- b. Within 10 days after using emergency contraceptives.
- c. Within 14 days after using emergency contraceptives.
- d. Within 21 days after using emergency contraceptives.
- e. Within 28 days after using emergency contraceptives.

15. Medical experts believe that emergency contraceptives work by:

- a. Inhibiting or delaying ovulation.
- b. Altering transport of sperm or egg.
- c. Damaging an embryo after it has become implanted in the endometrium.
- d. Answers a and b both are correct.
- e. All of the above answers are correct.

16. The medical definition of pregnancy states that pregnancy begins:

- a. With fertilization of an egg.
- b. During transport of the fertilized egg from the Fallopian tube to the uterus.
- c. When cell division begins in a fertilized egg.
- d. With implantation of the blastocyst in the endometrium.
- e. None of the above answers is correct.

17. Collaborative practice agreements:

- a. May permit pharmacists to initiate, monitor, or adjust drug therapy.
- b. Are agreements between a pharmacist and an independent prescriber.
- c. Are permitted by at least 25 states within the United States.
- d. Are usually based on a written protocol.
- e. All of the above answers are correct.

18. Conscience clauses are policies that:

- a. Ask pharmacist employees to notify employers at the earliest opportunity if they have a moral or religious objection to dispensing certain types of prescriptions.
- b. Ask employers to reasonably accommodate the religious or moral beliefs of an employee pharmacist.
- c. Include provisions that will facilitate access to prescribed medications in a timely manner.
- d. Are recognized by the APhA as a means to balance the needs of the patients and the religious or moral beliefs of the pharmacist.
- e. All of the above answers are correct.

19. The use of Plan B is contraindicated in women with:

- a. Undiagnosed abnormal genital bleeding.
- b. Acute focal migraine.
- c. A history of thromboembolism.
- d. Heart disease.
- e. Severe liver disease.

C.E. Credit:

To obtain 2 hours of continuing education credit (0.2 CEU) for "Emergency Contraception: The Pharmacist's Role," complete the assessment exercise, fill out the "C.E. Credit" page at the end of this publication, and return that page to APhA. A certificate will be awarded for a passing grade of 70% or better. Pharmacists who complete this exercise successfully before May 15, 2003, can receive credit.



The American Pharmaceutical Association is approved by the American Council on Pharmaceutical Education as a provider of continuing education. APhA provider number: 202-000-00-116-H01.

"Emergency Contraception: The Pharmacist's Role," is a home-study continuing education program for pharmacists developed by the American Pharmaceutical Association and supported by the Reproductive Health Technologies Project, Women's Capital Corporation, makers of Plan B.

20. Based on product labeling, which of the following emergency contraceptives should be avoided in women with a history of stroke or thromboembolism?

- a. Preven.
- b. Plan B.
- c. A copper-containing IUD.
- d. Ovrette.
- e. All of the above answers are correct.

C.E. Credit

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EXAMINATION

Please circle your answers
(one answer per question).

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

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| _____ Good | _____ Poor |

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How well did this program achieve its educational objectives?

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| _____ Very well | _____ Somewhat |
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