

# Pharmacists and Emergency Birth Control

## Overcoming Barriers to Access for Young Women in South Carolina.

There are about three million unintended pregnancies in the United States each year, and nearly half of these pregnancies end in abortion. However, women can use emergency birth control pills *after* sexual intercourse to *prevent* pregnancy. Emergency birth control pills are up to 89 percent effective in preventing pregnancy, depending on how quickly they are begun, the type of pill taken, and when the sex occurred during a woman's menstrual cycle.<sup>1,2,3</sup> A woman may use this medication whenever she has had unprotected sex and is at risk of unintended or unwanted pregnancy – regardless of whether the risk was due to coercion, improper use of a method, method failure, or nonuse of any method.

Emergency birth control pills are entirely safe, do *not* cause abortion, and cause no harm to a woman or her pregnancy, if she is already pregnant. Studies show that very few women use emergency contraception more than once, and most are already using a regular method of contraception. The American Pharmacists Association recommends that pharmacists: 1) help overcome barriers to the use of emergency contraception by educating their clients and other health professionals and 2) develop effective counseling skills and sensitivity to the stress that women may be experiencing when they seek emergency birth control pills.<sup>1</sup>

### Regimen

Emergency birth control pills are hormonal contraception—specifically, the same type of hormonal contraception that comprises regular birth control pills. Regimens include levonorgestrel-only (progestin-only) and the Yuzpe regimen of combined estrogen and progestin.

- The levonorgestrel-only regimen consists of either: a) 1.50 mg of levonorgestrel in a single dose; or b) two doses of 0.75 mg each, taken up to 12 hours apart.
- The combined estrogen-progestin regimen consists of two doses, taken 12 hours apart, of 100 mcg ethinyl estradiol plus 0.50 mg of levonorgestrel.<sup>1,2,3</sup>

*The latest research shows that levonorgestrel, taken in a 1.50 mg single dose, is the most effective regimen and has the fewest side effects.*<sup>1,2,3</sup>

### Availability

In 1997, FDA recognized the use of combined oral contraceptives as being safe and effective as emergency contraception.<sup>4</sup> In 1999, the FDA approved the levonorgestrel product Plan B<sup>®</sup> for use as emergency contraception.<sup>5</sup>

Emergency birth control pills meet all the FDA's requirements for nonprescription status: 1) a woman can, and indeed always does, self-diagnose her need for emergency contraception; 2) swallowing pills does not require medical supervision; and 3) the medication is safe and effective. In 2004 therefore, the FDA's joint advisory committee on women's reproductive health voted 23 to four in favor of nonprescription status for Plan B<sup>®</sup>.<sup>6</sup> Although the FDA denied nonprescription status for Plan B<sup>®</sup> at that time, it has since approved dual labeling status for Plan B<sup>®</sup>. In August 2006, the Food and Drug Administration (FDA) ruled that young women (and men) ages 18 and older can obtain Plan B<sup>®</sup>, the only prepackaged, dedicated emergency birth control pill product, without a prescription; younger women will still need a prescription for Plan B<sup>®</sup>. Other than Plan B<sup>®</sup>, providers may prescribe and pharmacists may dispense various brands of birth control pills as emergency contraception.<sup>1,3</sup> A current list of eligible contraceptive brands and the appropriate number of pills to dispense is available at the Web site [ec.princeton.edu](http://ec.princeton.edu).

### Efficacy

Emergency birth control pills are effective in preventing pregnancy after unprotected sex and most effective when begun within 12 to 24 hours after sex. The pills remain effective when used up to 72 hours after sex. Some studies also indicate that they continue to be effective, although somewhat less so, when used up to 120 hours after sex.<sup>1,2,3</sup> Studies indicate that efficacy declines substantially over time.<sup>1,2,3,7</sup>

The levonorgestrel-only regimen is more effective than the combined estrogen-progestin regimen.

- Four studies of the levonorgestrel regimen in almost 5,000 women showed that it reduced a woman's chance of pregnancy by up to 93 percent (range 60 to 93 percent).<sup>3,8,9,10,11</sup>
- A meta-analysis of eight studies of the combined estrogen-progestin regimen in over 3,800 women concluded that this regimen prevented about 74 percent of pregnancies (range 56 to 89 percent).<sup>12</sup>
- Finally, a randomized trial compared the two regimens and found that the chance of pregnancy among women who received the levonorgestrel-only regimen was about one-third (0.36) the chance among those who received the combined regimen.<sup>3,9</sup>

## Action

Emergency birth control pills work like regular birth control pills to prevent pregnancy. The primary mechanism of action of combined and progestin-only pills is to delay or inhibit ovulation. The pills may inhibit fertilization.<sup>13</sup> It is possible, though *unproven*, that emergency birth control pills may also prevent implantation. The medical community widely agrees that pregnancy begins when implantation is complete.<sup>2,3</sup>

Emergency contraception is sometimes confused with medical abortion (also known as RU486/mifepristone), but emergency birth control pills are not an abortifacient.<sup>1</sup> Whereas medical abortion terminates an existing pregnancy, the pills are effective only *before* a pregnancy is established. Emergency birth control pills can prevent pregnancy during the five or more days between intercourse and implantation.<sup>1,2</sup>

## Safety

Emergency birth control pills are entirely safe. In fact, the American College of Obstetricians & Gynecologists, American Academy of Pediatrics, Society for Adolescent Medicine, and World Health Organization assert that this medication is entirely safe even for women for whom regular birth control pills are unsafe as well as those for whom pregnancy is a serious risk.<sup>2,14,15,16</sup> (See World Health Association findings below.)

Emergency birth control pills do not cause birth defects. Over 40 years experience with birth control pills has shown no risk of birth defects if a woman is already pregnant. This evidence applies, as well, to the use of birth control as an emergency medication. Emergency birth control pills are contraindicated for pregnant women *only* because they will *not* end a pregnancy.<sup>1,2,3,15,16</sup> Even studies of older, higher-dose oral contraceptives have shown that emergency birth control pills confer no increased risk to an established pregnancy or harm to a developing embryo.<sup>1,2</sup> Because emergency use of the pills is not dangerous under any known circumstances, routine screening – such as pelvic exam or pregnancy and/or blood test – is entirely unnecessary, and experts say that administration of emergency contraception should *not* be delayed in order to perform *any* test.<sup>2,3,14,15</sup>

## Side Effects

Side effects, especially from the combined regimen, can include nausea, vomiting, abdominal pain, fatigue, headache, dizziness, breast tenderness, and irregular vaginal spotting or bleeding. The levonorgestrel-only regimen carries significantly lower chance than the combined regimen of causing nausea and vomiting. In most women, menses will occur within a week before or after the time they would have expected it.<sup>1,2,3</sup>

To minimize nausea and vomiting, the American College of Obstetricians & Gynecologists, the Society for Adolescent Medicine, and International Consortium for Emergency Contraception recommend the levonorgestrel-only regimen in preference to the combined regimen.<sup>2,3,14</sup> Meanwhile, women given the combined regimen should receive *pretreatment* with antiemetic drugs (medizine or metoclopramide). If vomiting occurs within two hours after either dose, women should repeat the dose. In cases of severe vomiting, vaginal administration of emergency birth control pills may be effective.<sup>2,3</sup>

## Statements of Prominent Medical Organizations regarding Emergency Birth Control Pills\*

- **American Pharmacists Association:** APhA supports the voluntary involvement of pharmacists, in collaboration with other health care providers, in emergency contraceptive programs that include patient evaluation, patient education, and direct provision of emergency contraceptive medications. APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient's access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal.<sup>17</sup>

A regimen that uses levonorgestrel alone is the emergency contraceptive regimen of choice because it is more effective and better tolerated than the Yuzpe regimen. . . . 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.<sup>1</sup>

- **American College of Obstetricians & Gynecologists:** Emergency contraception should be offered to women who have had unprotected or inadequately protected sexual intercourse and who do not desire pregnancy. . . . The levonorgestrel-only regimen is more effective and is associated with less nausea and vomiting and should, if available, be used in preference to the combined estrogen-progestin regimen. . . . Prescription or provision of emergency contraception in advance of need can increase availability and use. . . . No clinical examination or pregnancy testing is necessary before provision or prescription of emergency contraception. . . . Emergency contraception may be made available to women [who have] contraindications to the regular use of conventional oral contraceptive preparations.<sup>2</sup>
- **American Academy of Pediatrics:** Emergency contraception has the potential to further decrease the rate of unintended teen pregnancies in the United States. . . . Education and counseling about emergency contraception should be part of the annual preventive health care visit for all teen and young adult patients when sexuality issues are addressed. . . . Advance prescription should be considered for teens and young adults. . . . An increase in awareness and availability of

\* Except where noted by brackets, these are exact quotations from the cited documents.

emergency contraception does not change reported rates of sexual activity or increase the frequency of unprotected intercourse among adolescents. . . . The AAP continues to support improved availability of emergency contraception to teens and young adults, including over-the-counter access and limiting the barriers to access placed by some health care providers and venues.<sup>14</sup>

- **Society for Adolescent Medicine:** Adolescent health care providers are encouraged to counsel all adolescents about ECPs [emergency contraceptive pills] during visits for acute as well as routine health care... All female adolescents being treated for sexual assault should be counseled about ECPs and offered a complete course of ECP treatment at that time. . . . Provision of ECPs should not be contingent on an adolescent's receiving pregnancy testing, pelvic examination, Pap smear, or STI testing. . . . Health care providers should provide progestin-only ECPs as the regimen of choice because of higher efficacy and lower side effects. Adolescents should be counseled to *take both pills at once* [emphasis added][rather than the current FDA-approved regimen of the first tablet immediately and the second 12 hours later].<sup>15</sup>
- **American Medical Association:** It is the policy of the AMA to enhance efforts to expand access to emergency contraception, including making emergency contraceptive pills more readily available through hospitals, clinics, emergency rooms, acute care centers, and physicians' offices. . . . Emergency contraception is considered safe and effective by the medical community as a whole. . . . Given that ECPs [emergency contraceptive pills] are more effective the sooner they are used, the Council believes establishing prescription and dispensing mechanisms that are convenient for women is crucial to their ability to use the therapy effectively... Physicians could also work . . . to arrange immediate care for women who call seeking emergency contraceptive treatment.<sup>18</sup>
- **American Medical Women's Association:** AMWA agrees with respected organizations such as the National Institutes of Health and the American College of Obstetricians and Gynecologists (ACOG) in defining pregnancy as beginning with implantation. . . . Emergency contraceptive pills work prior to implantation and therefore are considered by these respected organizations and AMWA as a contraceptive, not as an abortifacient. Emergency contraceptive pills do not affect an established pregnancy and numerous studies of the teratologic risk of conception during regular use of oral contraceptives (including the use of older, higher-dose preparations) found no increase in risk. AMWA affirms its commitment to supporting reproductive choice for women and believes that emergency contraception is an important option. AMWA is committed to promoting awareness of and improving access to emergency contraception for women of diverse ethnic and socioeconomic backgrounds.<sup>19</sup>
- **American Nurses Association:** There are safe and effective measures available for emergency contraception. . . . As nurses, [we] individually and collectively, can educate school administrators, parents and other policy makers about the severity of the public health issues of teen pregnancy, STDs, and sexual abuse in the community and in this country. . . . [We] can advocate on behalf of more comprehensive approaches for educating teens in practice settings, community, and schools. . . . [We] can be sure that there are available and affordable and non-punitive resources for teens to obtain contraceptive information and protection in [the] community.<sup>20</sup>

The position of these respected medical associations is strongly supported by the findings of the World Health Organization.

- **World Health Organization:** *Medical eligibility criteria* include no conditions in which risks of emergency contraceptive pills outweigh the benefits. Evidence strongly supports ECP use in women who: are breastfeeding; have a history of ectopic pregnancy; have been raped; and/or have a history of repeated use of ECPs. In addition, because the use of ECPs is less than in the regular use of contraceptive oral pills (and ECPs, thus, have less clinical impact), the World Health Organization's review of the medical literature found that ECPs are appropriate for use in women with a history of cardiovascular complications, angina pectoris, migraine, and/or severe liver disease.<sup>16</sup>

### Obtaining Emergency Birth Control Pills at Pharmacies in South Carolina

In summer 2006, volunteers held phone interviews with staff in 82 pharmacies in four South Carolina cities (Charleston, Columbia, Greenville, and Spartanburg) and with staff in 57 pharmacies in neighboring communities.<sup>21</sup> The pharmacies were all chain stores, including CVS, Eckerd, K-Mart, Kerr Drug, Wal-Mart, and Walgreen. Staff successfully completed 132 interviews.

- Staff in 67 percent of pharmacies could fill a prescription for Plan B<sup>®</sup> that same day. Of those that could not fill a prescription that day, 41 percent said they could fill the prescription within 24 hours and 11 percent, within 48 hours.
- Staff in 13 percent (n=17) of pharmacies could not fill a prescription for Plan B<sup>®</sup> in a timely manner but gave the name of another pharmacy that could.
- Among 132 pharmacies, staff in six percent (n=8) said they could not provide Plan B<sup>®</sup> because it was illegal or unavailable in the United States; an unknown drug; or something that their warehouse did not provide because no one wanted it.
- Prices for Plan B<sup>®</sup> ranged widely – from \$20 to \$84 and averaging \$39 across all pharmacies that provided it.

In South Carolina, young women's access to emergency birth control pills in the form of Plan B<sup>®</sup> is better than it is in some other states. But it can be better. Since this medication is most effective the sooner it is taken, any delay in putting Plan B<sup>®</sup> into the hands of young women increases their risk for unintended pregnancy.

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# FROM RESEARCH TO PRACTICE

## Serving Young Women Who Seek Emergency Birth Control Pills

Pharmacists can help young women get emergency birth control pills quickly – within 72 hours after unprotected sex. In addition, pharmacists can encourage young women under 18 to get a prescription for the pills before they need them and to have it on hand, *just in case of emergency*.

Pharmacists can also:

- Provide non-judgmental customer care to young people, regardless of their age.
- Treat young women with sensitivity, recognizing that they are probably experiencing considerable stress as a result of whatever has caused their need for emergency contraception.
- Learn all the facts about emergency birth control pills. Read *APhA Special Report, Emergency Contraception: The Pharmacist's Role*; visit [www.aphanet.org](http://www.aphanet.org).
- Educate your customers about emergency birth control pills. Offer brochures, wallet cards, and/or prescription inserts about the medication. Contact the South Carolina Emergency Contraception Initiative for publications and training.
- Refer your young clients to a medical provider for a prescription. Visit [ec.princeton.edu](http://ec.princeton.edu) to find a nearby provider who will write prescriptions for emergency birth control pills, especially Plan B®.
- Work with others to pass a collaborative practice law in South Carolina. Visit [www.pharmacyaccess.org](http://www.pharmacyaccess.org) for more information.
- Keep Plan B® in stock so people under age 18 can get their prescriptions filled quickly and so that women ages 18 and over can pick it up when they need it.

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