

## Emergency Contraception — History and Access

Every woman deserves every chance to prevent an unintended pregnancy. Emergency contraception (EC) provides women with a second chance at prevention in cases of unanticipated sexual activity, contraceptive failure, or sexual assault. EC has been available for more than 30 years. It is a safe and effective method of contraception, and women who have used it report high levels of satisfaction.

Despite its enormous potential, anti-choice groups oppose the use of EC. In order to hinder women's access to this important method of contraception, they falsely claim that EC ends a pregnancy, and they disseminate other misinformation about its safety and effectiveness.

Fortunately, public awareness and availability of EC has increased, and hopefully more women will benefit from this important backup birth control method in the future.

### **Emergency contraception is not just a "morning-after pill." Multiple emergency contraception options are available.**

EC can reduce the risk of pregnancy after unprotected intercourse. It is provided in three ways: using a progestin-only branded product — Plan B<sup>®</sup>; using hormonal contraceptive pills — either progestin-only birth control pills or combined oral contraceptives; or inserting a copper-releasing IUD (intrauterine device).

### **Progestin-only emergency contraception**

On July 28, 1999, the U.S. Food and Drug Administration (FDA) approved the first progestin-only EC available in the U.S. Produced by Barr Pharmaceuticals, Inc., and known as "Plan B," it consists of two pills, taken 12 hours apart or all at once, and contains only the hormone levonorgestrel, a progestin. While this treatment is more effective

the sooner it begins, Plan B can be started up to 120 hours (five days) after unprotected intercourse (von Hertzen et al., 2002). Plan B contains no estrogen ("FDA Approves...", 1999).

Off-label administration of progestin-only oral contraceptives is also effective, but it requires taking 20 Ovrette<sup>®</sup> oral contraceptive pills, and then taking another dose of 20 pills 12 hours later (Stewart et al., 2004).

Studies have shown that a single administration of two full doses of either Plan B or progestin-only birth control pills is also effective (ACOG, 2005; von Hertzen et al., 2002).

### **Yuzpe regimen**

This method of EC is named for Canadian Professor A. Albert Yuzpe, who published the first studies demonstrating the method's safety and effectiveness in 1974. This regimen uses two doses of oral contraceptive pills that combine estrogen and certain progestins (FDA, 1997). It can reduce the risk of pregnancy if taken within 120 hours (five days) of unprotected intercourse. The treatment is more effective the sooner it begins (Ellertson et al., 2003; "FDA Approves...", 1999; Rodrigues et al., 2001; Stewart et al., 2004). (Because EC has a five-day window of effectiveness, the popular term "morning-after pill" is misleading.) The doses are taken 12 hours apart.

### **Many common oral contraceptive pills can be used as emergency contraception, although their manufacturers do not label the pills for this use.**

"Off-label" use of approved medications is legal and commonplace in American medicine. Further, in February 1997, the FDA declared emergency use of birth control pills, following the Yuzpe regimen, to be safe and effective. At that time, six suitable pill

brands were available on the U.S. market (FDA, 1997). Currently, the following brands can be used as EC in the U.S.:

<u>Pill Brand</u>	<u>Manufacturer</u>	<u>Pills per Dose</u>
Alesse <sup>®</sup>	Wyeth-Ayerst	5 pink pills
Aviane <sup>®</sup>	Barr	5 orange pills
Cryselle <sup>®</sup>	Barr	4 white pills
Enpress <sup>®</sup>	Barr	4 orange pills
Jolessa <sup>™</sup>	Barr	4 pink pills
Lessina <sup>®</sup>	Barr	5 pink pills
Levlen <sup>®</sup>	Berlex	4 light-orange pills
LevLite <sup>®</sup>	Berlex	5 pink pills
Levora <sup>®</sup>	Watson	4 white pills
Lo/Ovral <sup>®</sup>	Wyeth-Ayerst	4 white pills
Low-Ogestrel <sup>®</sup>	Watson	4 white pills
Lutera <sup>™</sup>	Watson	5 white pills
Lybrel <sup>®</sup>	Wyeth-Ayerst	6 yellow pills
Nordette <sup>®</sup>	Wyeth-Ayerst	4 light-orange pills
Ogestrel <sup>®</sup>	Watson	2 white pills
Ovral <sup>®</sup>	Wyeth-Ayerst	2 white pills
Portia <sup>®</sup>	Barr	4 pink pills
Quasense <sup>™</sup>	Watson	4 white pills
Seasonale <sup>®</sup>	Barr	4 pink pills
Seasonique <sup>™</sup>	Barr	4 light-blue-green pills
Tri-Levlen <sup>®</sup>	Berlex	4 yellow pills
Triphasil <sup>®</sup>	Wyeth-Ayerst	4 yellow pills
Trivora <sup>®</sup>	Watson	4 pink pills

(OPR, 2009).

### The IUD

A copper-releasing IUD (ParaGard<sup>®</sup>) can be inserted within five days of unprotected intercourse as a method of EC (WHO, 2004). It can be left in place for up to 12 years for very effective contraception. Or the IUD can be removed after the next menstrual period, when it is certain that pregnancy has not occurred (Hatcher et al., 2005).

### Emergency contraception reduces the risk of pregnancy by up to 95 percent, and emergency contraception IUD insertion reduces the risk by 99.9 percent.

Two factors influence the effectiveness of EC: the amount of time elapsed after unprotected intercourse, and the point in a woman's cycle at which she had sex. The earlier EC is taken after unprotected intercourse, the more effective it is (TFPMFR, 1998). The closer a woman is to ovulation at the time of unprotected intercourse, the less likely the method will succeed (Stewart et al., 2004). EC is not as effective as correct and consistent use of ongoing reversible contraceptive methods such as the pill, IUD, or contraceptive implants, injections, patches, or rings, and it does not protect against sexually transmitted infections

(STIs) (Knowles & Ringel, 1998; Roumen et al., 2001; Ziemann et al., 2002).

- The Yuzpe regimen of combined estrogen and progestin EC reduces the *risk* of pregnancy by roughly 75 percent if started within 72 hours of unprotected intercourse. Not every woman *at risk* of pregnancy actually becomes pregnant. On average, only eight out of 100 women will become pregnant after having unprotected sex during the second or third week of their menstrual cycles. But if they take EC, only two out of those 100 women will become pregnant. Combined hormone EC reduces the risk of pregnancy by roughly 75 percent, preventing six of eight likely pregnancies (Knowles & Ringel, 1998; OPR, 2005; Rodrigues et al., 2001; Stewart et al., 2004).
- When used within 72 hours of unprotected intercourse, progestin-only EC was found to reduce the risk of pregnancy by 89 percent in a World Health Organization-supported study involving nearly 2,000 women in 21 clinics around the world. When taken within 24 hours of unprotected intercourse, progestin-only EC was found to reduce the risk of pregnancy by 95 percent ("FDA Approves...", 1999; TFPMPFR, 1998).

Only 10 pregnancies occurred after more than 9,400 emergency insertions of copper-bearing IUDs since 1976: a rate of fewer than one in 1,000, reducing the risk of pregnancy by more than 99 percent (OPR, 2005; Stewart et al., 2004).

### Emergency contraception is a safe backup method of birth control.

Millions of women around the world have used EC safely and effectively (Glasier, 1997; Guillebaud, 1998). But EC is less effective than the most popular ongoing methods of contraception, and in general practice, women only turn to EC in emergencies — as a backup to their usual birth control method.

Nearly every woman who needs EC can safely use it — even women with contraindications to the ongoing use of oral contraceptives (Guillebaud, 1998; Hatcher et al., 2005). EC can also be used safely by adolescents. One study designed to evaluate the safety of EC use in teenagers enrolled 52 teens between the ages of 13 and 16. EC was found to be safe and well tolerated by the teens. They took the medicine properly, and they returned to their normal menstrual cycles at the same rate as adult women taking EC (Harper et al., 2004).

EC should not be used by women who are already pregnant, not because the pills are thought to be harmful, but because they are ineffective at terminating established pregnancies (Stewart et al., 2004).

### **Emergency contraception is not a method of abortion.**

EC cannot end a pregnancy. According to the FDA, "Emergency [contraception is] not effective if the woman is pregnant ..." (FDA, 1997). A study in 2002 found that, most often, EC reduces the risk of pregnancy by inhibiting ovulation (Marions et al., 2002). More recent studies demonstrate that progestin-only EC works only by preventing ovulation or fertilization and has no effect on implantation (Croxatto et al., 2003; Ortiz et al., 2004). Scientific authorities agree that EC reduces the risk of pregnancy and helps prevent the need for abortion; it itself is not a form of abortion (Grimes, 1997; Guillebaud, 1998; Hughes, 1972; Stewart et al., 2004). In its Statement on Mechanism of Action, the International Consortium for Emergency Contraception and the International Federation of Gynecology & Obstetrics reported that hormonal EC cannot inhibit implantation or harm the embryo (ICEC & FIGO, 2008).

Ongoing use of the copper IUD prevents fertilization by releasing copper, which alters fluids in the uterus and fallopian tubes to act as spermicide (Grimes, 2004; Hatcher et al., 2007). In theory, ongoing use of the copper IUD may prevent implantation by thinning the endometrial lining of the uterus, but there is no scientific evidence that this actually happens (Alvarez et al., 1988; FHI, 2005). Emergency insertion of a copper IUD may work somewhat differently than ongoing use. It may prevent fertilization, but it may also prevent implantation (Stewart et al., 2007).

### **Progestin-only emergency contraception greatly reduces side effects.**

- Combined hormone EC induces nausea in 30–50 percent of women, and vomiting in 15–25 percent of women. Anti-nausea or anti-emetic medications taken one hour before ingesting EC may reduce these side effects. Breast tenderness, fatigue, irregular bleeding, abdominal pain, headaches, and dizziness may also occur. These side effects usually taper off one or two days after ingesting EC (Knowles & Ringel, 1998; Raymond et al., 2000; Stewart et al., 2004).

- Nausea and vomiting are far less common using progestin-only EC than using the Yuzpe regimen (Stewart et al., 2004). In a World Health Organization-supported study using levonorgestrel, nausea occurred in 23.1 percent of cases, and vomiting in 5.6 percent. Other side effects were also less common (TFPMFR, 1998).
- In about 10–15 percent of women treated, EC changes the amount, duration, and timing of the next menstrual period. This effect is usually minor, and menstruation occurs a few days earlier or later than expected (Hatcher et al., 2005). If EC is used frequently, periods may become irregular and unpredictable (Knowles & Ringel, 1998).
- Side effects of IUD insertion may include abdominal discomfort, vaginal bleeding or spotting, and infection. Possible side effects of IUD use include heavy menstrual flow, cramping, infection, infertility, and uterine puncture (Grimes, 2004; Stewart et al., 2004).
- Neither EC nor IUDs prevent the spread of sexually transmitted infections, including HIV. Many women who need EC are at risk of these infections. At heightened risk are those who have had unprotected sex with infected partners, those who use IV drugs or have a partner who does, and victims of sexual assault. For those at risk of sexually transmitted infections, hormonal EC is likely to be a safer choice than emergency IUD insertion (Knowles & Ringel, 1998). During IUD insertion, bacteria from a preexisting infection can be introduced into the sterile uterine cavity — untreated, such infections can lead to pelvic inflammatory disease. HIV infection can also increase the risk of pelvic inflammatory disease associated with an IUD (Grimes, 2004).
- Women should discuss with their clinicians any sign of pregnancy after using EC. The signs include a missed menstrual period, nausea, inexplicable fatigue, sore or enlarged breasts, headaches, and frequent urination (Cunningham et al., 1997; Stewart et al., 2004).
- EC, like other contraceptives, decreases the risk of ectopic pregnancy — a pregnancy that develops outside the uterus — by reducing the risk of pregnancy (ACOG,

2005). However, in the event of pregnancy following the use of EC, a clinician should test for ectopic pregnancy. Ectopic pregnancies, left untreated, will cause complications that can cause death. Women should seek medical attention if they have signs of ectopic pregnancy, which include severe pain on one or both sides of the lower abdomen, abdominal pain and spotting, especially after a very light or missed menstrual period, and faintness or dizziness (Knowles & Ringel, 1998; Stewart et al., 2004).

### **Users of emergency contraception report high levels of satisfaction.**

- A study of 235 women who had used EC found that the overwhelming majority — 91 percent — were satisfied with the method, and 97 percent would recommend it to friends and family. These women also reported that they did *not* intend to substitute EC for regular contraceptive use (Harvey et al., 1999).
- Of 119 women who obtained EC at Planned Parenthood® of New York City clinics, 92 percent stated that they would use the method again if necessary, but reported that they believed EC should be reserved for emergencies. Three-fourths of the sample indicated that since using EC, they were *more* likely to use ongoing methods of contraception (Breitbart et al., 1998).

### **Anti-choice organizations, pharmacists, religious hospitals, and hotline difficulties threaten women's access to emergency contraception.**

- Major anti-choice organizations such as the American Life League, Human Life International, and Stop Planned Parenthood International oppose EC and have launched national and international misinformation campaigns claiming that it works by causing abortion (ALL, 1997; Gallagher, 1998; STOPP International, 2000). In addition, they falsely assert that testing has not been done to confirm the safety of EC (ALL, 1997); they underreport statistics on the effectiveness of EC (STOPP International, 2000), and they dismiss evidence of decreased side effects of progestin-only EC (Clarke, 2000).
- Individual pharmacists have refused to fill prescriptions for EC, presumably based on

the false assumption that EC works by causing abortion (Cohen, 1999). This problem received widespread attention in May 1999, when Wal-Mart® announced that it would not sell PREVENT™ — a combined hormone EC that is no longer on the market — in its approximately 2,400 pharmacies (Canedy, 1999). In February 2004, a Denton, TX, pharmacist refused to fill a rape survivor's prescription for EC, citing "religious convictions" (Austin, 2004). A survey of 195 pharmacies in New York City revealed that 25 percent did not carry EC, and of those, none had posted signs required by law, saying they do not carry the pills (Andreatta, 2004).

- Although the *Ethical and Religious Directives for Catholic Health Care Services* states that "A female who has been raped should be able to defend herself against a potential conception from the sexual assault" (USCCB, 2001), many Catholic hospitals do not provide EC, even to rape survivors. A study of the nation's nearly 600 Catholic hospital emergency rooms found that only 28 percent offered EC to women who had been raped (CFFC, 2002). Sometimes a Catholic hospital is a community's only provider — leaving sexual assault survivors with very little chance of being taken to a hospital that will provide them with EC.
- An evaluation of the Emergency Contraception Hotline found that while at least 76 percent of callers were able to obtain a telephone prescription or an appointment with a hotline provider within 72 hours of unprotected intercourse, 11 percent failed (Trussell et al., 2000). Although the hotline provides an important resource for women seeking EC, lack of available appointments and limited practice hours necessitate additional venues to facilitate access.

### **Efforts to improve access to emergency contraception**

In 1999, France became the first country in the world to distribute a brand of EC — NorLevo® — in pharmacies without prescription or parental consent. NorLevo is also distributed free-of-charge along with other methods of contraception at family planning centers (Ollivier, 1999).

In January 2000, France's Deputy Education Minister Segolene Royal took the unprecedented

step of granting its school nurses the right to dispense EC in both junior and high schools (Daley, 2000; McNeil, 2000). The initiative was accompanied by a nationwide sex education campaign that included information on EC. Provision of EC in schools received widespread support from students, health practitioners, and the union of school nurses (McNeil, 2000; Ollivier, 1999).

However, in July 2000 the Council of State, France's highest administrative court, overruled this decision citing a 1967 law that says hormonal contraception may only be distributed under prescription by pharmacies. The ruling followed a strong show of opposition by the Catholic Church and was lauded by the National Confederation of Catholic Family Associations, which also expressed regret that the court did not take additional steps to reaffirm parental authority in such matters (McNeil, 2000). In October 2000, the French Parliament amended the law to once again allow school nurses to dispense emergency contraception (Kolata, 2000).

Restrictions on the dispensing of EC began to ease in other countries, as well. By 2006, women in 42 other countries, including Albania, Belgium, Canada, Denmark, Finland, India, Israel, Morocco, Norway, Portugal, South Africa, Sweden, and the United Kingdom, could obtain EC without a prescription (Trussell & Wynn, 2006).

In the United States, steps were taken to make EC available over the counter (OTC) or via collaborative practice agreement. In July 1997, an EC collaborative drug therapy agreement pilot project was launched in Washington State. Collaborative drug therapy agreements between pharmacists and prescribers, such as physicians or nurse practitioners, grant the pharmacist the authority to write prescriptions under a set of prescribing protocols. In the first 13 months of the project in the state of Washington, 9,333 EC prescriptions were provided, preventing between 504 and 2,100 pregnancies — about half of which would have ended in abortion ("Pharmacists, Providers...", 1999). Similar programs were established in Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Vermont, and other states considered legislation that would allow pharmacists to dispense emergency contraception without a prescription (Greenberger, 2005; Haddix, 2004; Neergaard, 2005; "Vermont Law...", 2006).

At public hearings held in June 2000, advocates, including the National Women's Health Network, the Reproductive Technologies Project, and the National Abortion and Reproductive Rights Action League,

testified at the FDA in support of reclassifying EC as an OTC drug ("Advocates Testify...", 2000). Prominent groups such as the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Medical Association, the American Medical Women's Association (AMWA), the American Public Health Association, and Planned Parenthood Federation of America voiced support of making EC available OTC or through a pharmacist (ACOG, 2001; AMWA, 1996; Foubister, 2001; Guttmacher Institute, 2005).

These organizations agreed that improving women's access to EC would not increase their reliance on it as a primary method of birth control. A study found that women who were given EC to take home used other birth control methods at the same rate as women who did not have the pills in their medicine cabinets. Women who had the pills at home were *more likely* to use EC once. But they were *not* more likely to use it repeatedly. Women who had home access to EC used the method correctly 98 percent of the time and had fewer unintended pregnancies than those who did not have EC at home (Glasier & Baird, 1998).

On February 14, 2001, the Center for Reproductive Rights filed a petition with the FDA on behalf of more than 70 medical, public health, and other organizations, to grant OTC status to EC (CRR, 2003). No decision was ever issued for this petition. The makers of Plan B filed a second petition in 2003. In December 2003, two FDA advisory panels found that Plan B met the criteria for availability without a prescription, and recommended granting OTC status. Five months later, despite these recommendations, the FDA chose to deny the petition, citing concerns about adolescent use and potential increases in promiscuity. A dozen members of Congress called for the resignation of key FDA officials for denying the OTC petition based on political and ideological — not scientific — reasons. Forty-one members of Congress asked that the FDA reconsider its decision (Kaufman, 2004).

The distributor of Plan B, Barr Pharmaceuticals, Inc., vowed to continue to work with health organizations and advocated to get the FDA to reverse its decision (Cox, 2004). Numerous studies have since been published that refute the FDA's claim that use of EC would lead to increased promiscuity. These studies demonstrate that while advanced access to EC does increase the chances of using EC, it does not alter sexual behavior or the risk for contracting STIs (Belzer et al., 2003; "Easy EC access ...," 2005; Marston et al., 2005; "Plan B", 2005; Raine et al., 2005).

- A study of adolescent mothers examined the impact of giving teenagers EC before they need it. One group of teen mothers received education about EC and was given an advance supply of the pills. Another comparison group received only education about EC. At the six-month follow-up, 83 percent of the group that received the pills used EC, as compared to only 11 percent of the education-only group. The group that received EC was not more likely to report having unprotected sex within the follow-up period (Belzer et al., 2005).
- Another study about advance provision of EC to adolescents had similar findings — the teenagers were more likely to use EC they received, and their use of condoms did not decrease (Harper et al., 2005).
- A 2004 study substantiated the findings of previous studies about advance provision. Adolescent women, aged 15 to 20, were randomized into two groups — one group received EC and education about EC, and the comparison group received education alone. In the first month of the study, the teens in the group that received the pills were twice as likely to use EC as the teens in the comparison group. They also took the pills an average of 10 hours sooner than the teens in the education-only group — an important finding because EC's effectiveness is time-limited. The two groups did not differ in their rates of hormonal contraceptive use at the six-month follow-up. Notably, the group that received the pills was more likely to report condom use at six months than the education-only group (Gold et al., 2004).

The FDA announced that it would, by January 21, 2005, issue its ruling on a subsequent application by Barr Pharmaceuticals, which requested OTC sale of EC to women who are 16 and older. The FDA did not meet its deadline (Baer, 2005). On August 26, 2005, while acknowledging that Plan B could be safely sold to women over the age of 17, the FDA announced yet another delay on deciding whether or not to make Plan B available over-the-counter. Citing concerns associated with the difficulty in enforcing OTC age restrictions, the FDA opened a 60-day public comment period to address EC OTC implementation strategies (Harris, 2005). This comment period ended November 1, 2005 (Harris, 2005; Kaufman, 2005).

On November 14, 2005, the Government Accountability Office (GAO) released its report on Plan B calling the handling of the application by the FDA "unusual." It found that the high-level involvement of top FDA officials was atypical, that the decision not to approve the application may have been made before the review was even completed, that Plan B was the only application in the last 10 years that did not receive approval according to the FDA's advisory committees recommendations, that no other FDA-approved contraceptive has age-related marketing restrictions, and that the rationale for not approving the application was *novel* (GAO, 2005).

In March 2006, Senators Hillary Clinton (D–NY) and Patty Murray (D–WA) brought the fight to bring EC OTC to the forefront of the Senate. They vowed to place a hold on the confirmation hearing for FDA Commissioner-nominee Andrew von Eschenbach until EC was approved for sale OTC.

On July 31, Barr Pharmaceuticals received a letter from Dr. von Eschenbach requesting that the company amend its application for the sale of Plan B. As acting commissioner of the FDA, von Eschenbach requested that the age restriction for the sale of Plan B be raised to 18 years, and that Barr Pharmaceuticals consider revising the packaging for EC and the location of sale — e.g., in pharmacies, where the age of the consumer could be closely monitored (Tanne, 2006).

On August 24, 2006, the FDA announced its approval of the sale of EC OTC to women and men 18 and older (Barr Pharmaceuticals, 2006). While Planned Parenthood was pleased that the FDA finally took action on this issue, we were troubled by the scientifically baseless restriction imposed on teenagers. Research shows that OTC access to EC does not increase or encourage sexual activity among teens, and better access to proven pregnancy prevention methods, such as accurate sex education and EC, is the best way to reduce the alarming rate of teen pregnancy nationwide.

On March 23, 2008, the U.S. District Court of the Eastern Division of New York ordered the FDA to permit the current manufacturer of Plan B — Duramed Research Inc. of Bala Cynwyd, PA — to make it available to women 17 and older without a prescription (Reuters, 2009). On April 22, 2009, the FDA announced that it would not appeal the court's decision and notified Duramed "that it may, upon submission and approval of an appropriate application, market Plan B without a prescription to women 17 years of age and older" (FDA, 2009).

Planned Parenthood is the leading provider of EC in the U.S. The number of women receiving EC from Planned Parenthood has grown from roughly 17,000 in 1995 to 1,423,365 in 2007 (PPFA, 1997; PPFA, 2008). Planned Parenthood offers all safe, available EC choices, but not every method is available at every Planned Parenthood health center. If you need a prescription for EC, contact your nearest Planned Parenthood health center at 1-800-230-PLAN.

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