Emergency Contraceptive Pills Information Packet

Unintended Pregnancy

What Are Emergency Contraceptive Pills?

How Do Emergency Contraceptive Pills Work?

Collaborative Drug Therapy Agreements

Expanding Access to Emergency Contraceptive Pills in Washington: Promoting Pharmacist/Prescriber Collaborative Agreements
Emergency Contraceptive Pills Information Packet

[Unintended Pregnancy]

What Are Emergency Contraceptive Pills?

How Do Emergency Contraceptive Pills Work?

Collaborative Drug Therapy Agreements

Expanding Access to Emergency Contraceptive Pills in Washington:
Promoting Pharmacist/Prescriber Collaborative Agreements
Unintended Pregnancy

The Problem
Unintended pregnancy is a problem of enormous magnitude in the United States. In 1994, the most recent year for which national statistics are available, there were over 2.65 million unintended pregnancies, accounting for almost half (49%) of all pregnancies. Unintended pregnancy impacts a significant proportion of the population. In 1994 about 48 percent of all women aged 15 to 44 had experienced an unintended pregnancy. Unintended pregnancy can result from contraceptive failure or non-use of contraception. Contraceptive failure accounts for about half of all unintended pregnancies.1

What Unintended Pregnancy Means to Women and Families
While it is certainly true that pregnancies that were not intended at the time of conception can result in healthy children and happy families, unintended pregnancy can have significant consequences. Approximately half of all unintended pregnancies end in abortion. When the pregnancy is carried to term, the child of an unintended pregnancy is at higher risk of negative outcomes such as low birth weight, dying in the first year of life, not receiving the resources necessary for healthy development, and being neglected or abused. The mother is at greater risk of depression, physical abuse, and not achieving her educational, financial, and career goals. Her relationship is at three times the risk of dissolution.2

Institute of Medicine Recommendations to Reduce Unintended Pregnancy
The Institute of Medicine’s 1995 landmark report The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families documents unintended pregnancy as a frequent and widespread problem with serious consequences imposing burdens on children, women, men, and families. The report specifically advocates an aggressive approach to increasing access to contraceptive services and recommends “broadening the range of health professionals and institutions that promote and provide methods of birth control.” In addition to broadening access, the report highlights the need to improve Americans’ knowledge about contraception.

The Role of Emergency Contraceptive Pills (ECPs) in Reducing Unintended Pregnancy
Emergency contraceptive pills can contribute to the Institute of Medicine’s goal to reduce unintended pregnancy by providing women with a method of preventing pregnancy after sex. ECPs can be used when a condom breaks, a diaphragm slips out of place, a woman misses two or more birth control pills in a row, or when no birth control is used. ECPs can contribute significantly to a strategy to reduce unintended pregnancy.

What are Emergency Contraceptive Pills?

Emergency contraceptive pills (ECPs) are a safe and effective method of preventing pregnancy after intercourse. Sometimes referred to as “morning after pills,” ECPs are a short, high dose of ordinary birth control pills taken within 72 hours of unprotected intercourse. Results from a recent international study suggest that the pills are more effective the sooner they are used. This short time frame makes easy access an important component of ECP service delivery.

Emergency contraceptive pills are not the same as RU-486, or mifepristone. RU-486 is used for early abortions in France, Great Britain, and China, but is not available in the United States.

Two types of emergency contraceptive pills are currently available:

- **Combined estrogen/progestin pills**
  Combined estrogen/progestin pills are the most commonly used emergency contraceptive method. Treatment must be initiated within 72 hours (3 days) of unprotected intercourse and requires two elevated doses of regular combined birth control pills taken 12 hours apart. Two approaches to the estrogen/progestin regimen can be used: one dedicated product, Preven, is packaged specifically for emergency contraceptive use in the United States, and regular birth control pills can be prescribed in special doses (see table).

- **Progestin-only pills**
  A progestin-only regimen is another effective method of emergency contraception. A recent World Health Organization study found that a progestin-only regimen of emergency contraception was both better tolerated (fewer women experienced negative side-effects such as nausea, vomiting, and fatigue) and more effective than the estrogen/progestin regimen.¹ Like the estrogen/progestin regimen, treatment must be initiated within 72 hours of unprotected intercourse and also requires two doses taken 12 hours apart. A dedicated progestin-only emergency contraception product is expected to be available in the United States by the summer of 1999. Until then, the only progestin-only product available for emergency contraceptive use in the United States requires that women take 20 pills for each dose (see table).
### Brands of Emergency Contraceptive Pills Available in the United States

<table>
<thead>
<tr>
<th>Brand</th>
<th>Manufacturer</th>
<th>Pills per Dose</th>
<th>Ethinyl Estradiol per Dose (µg)</th>
<th>Levonorgestrel per Dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dedicated Product</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preven</td>
<td>Gynétics</td>
<td>2 blue pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>Oral Contraceptive Pills</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ovral</td>
<td>Wyeth-Ayerst</td>
<td>2 white pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td>Alesse</td>
<td>Wyeth-Ayerst</td>
<td>5 pink pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td>Levite</td>
<td>Berlex</td>
<td>5 pink pills</td>
<td>100</td>
<td>0.50</td>
</tr>
<tr>
<td>Nordette</td>
<td>Wyeth-Ayerst</td>
<td>4 light-orange pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Levlen</td>
<td>Berlex</td>
<td>4 light-orange pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Levora</td>
<td>Watson</td>
<td>4 white pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Lo/Ovral</td>
<td>Wyeth-Ayerst</td>
<td>4 white pills</td>
<td>120</td>
<td>0.60</td>
</tr>
<tr>
<td>Triphasil</td>
<td>Wyeth-Ayerst</td>
<td>4 yellow pills</td>
<td>120</td>
<td>0.50</td>
</tr>
<tr>
<td>Tri-Levlen</td>
<td>Berlex</td>
<td>4 yellow pills</td>
<td>120</td>
<td>0.50</td>
</tr>
<tr>
<td>Trivora</td>
<td>Watson</td>
<td>4 pink pills</td>
<td>120</td>
<td>0.50</td>
</tr>
<tr>
<td>Ovrette</td>
<td>Wyeth-Ayerst</td>
<td>20 yellow pills</td>
<td>0</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Adapted from *Journal of the American Medical Women’s Association* EC Supplement 1998, page 213.

* The treatment schedule is one dose within 72 hours after unprotected intercourse, and a second dose 12 hours later.

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

How Do Emergency Contraceptive Pills Work?

Mechanism of Action
Emergency contraceptive pills (ECPs) prevent pregnancy through the same mechanisms as daily cyclical birth control pills: by inhibiting or delaying ovulation, stopping fertilization, or preventing implantation. The primary mechanism of action for ECPs is inhibiting ovulation, but statistical evidence suggests that ECPs work through more than one mechanism of action, otherwise they would not be as effective as they are.

Safety
Emergency contraceptive pills are safe and effective for preventing pregnancy after sex. In February 1997, the Food and Drug Administration (FDA) Commissioner concluded that “certain combined oral contraceptives containing ethinyl estradiol and norgestrel or levonorgestrel are safe and effective for use as postcoital emergency contraception.” The World Health Organization has stated that current evidence suggests that the amount of combined oral contraception used for emergency contraception is too small to have a clinically significant impact on conditions such as cardiovascular disease, angina, acute focal migraine, or severe liver disease. Both the World Health Organization and the International Planned Parenthood Federation have stated that there are no absolute contraindications for use of combined estrogen and progestin ECPs except pregnancy. The pregnancy exception relates to the fact that the regimen is not effective during pregnancy, not to any teratogenic effects. The American College of Obstetrics and Gynecology (ACOG) has developed a set of evidence-based guidelines for clinical issues surrounding emergency oral contraception. They state that no published studies using evidence-based criteria have reported contraindications to the use of ECPs. None of these studies followed subjects beyond the onset of pregnancy or resumption of menses, however, and no studies have specifically investigated outcomes among patients with contraindications to oral contraceptive use. ACOG concludes that some contraindications to the use of combined oral contraceptive pills are based on a presumption of long-term use and are not likely to pertain to the short duration of use required for emergency contraception.

Effectiveness
Emergency contraceptive pills reduce a woman’s risk of pregnancy after unprotected sex by about 75 percent. Typically, if 100 women had unprotected sex once during the second or third week of their cycle, 8 would become pregnant. With ECPs, only 2 would become pregnant.
**Pregnancy Prevention**

Over 50 percent of unintended pregnancies end in abortion. Emergency contraceptive pills can prevent abortion by preventing unintended pregnancy. The National Institutes of Health and the ACOG define pregnancy as beginning with implantation. It takes approximately six days after ovulation for the fertilized egg, or embryo, to begin implantation. Intervention within 72 hours after intercourse cannot result in abortion, because implantation does not begin within this time frame. ECPs do not interrupt an established pregnancy and are not effective if a woman is pregnant.

---

Collaborative Drug Therapy Agreements

Pharmacists are able to prescribe emergency contraceptive pills (ECPs) directly to women through a mechanism known as a collaborative drug therapy agreement. Collaborative drug therapy agreements are entered into voluntarily by a pharmacist and a licensed prescriber. Legislation authorizing collaborative agreements exists in 22 states, however the degree of prescriptive authority allowed to pharmacists varies significantly among states. In Washington State, legislation allowing collaborative agreements has been in place for 20 years and has been used for pharmacokinetic drug monitoring, parenteral nutrition, anticoagulant therapy, pain drug management, immunization, and refill medication protocols. Washington State legislation allows community pharmacists to develop collaborative agreements, and this is a key element in increasing ECP access.

Collaborative agreements are based on a protocol that specifically defines prescribing activities. The protocol is signed by both the prescriber and the pharmacist, and includes the following components: a definition of the eligible patients, the delegated prescribing activities (disease, drugs, or drug categories), a treatment plan or guideline that sets criteria for drug decision making, how the drug decisions will be documented, and how the authorized prescriber will be informed. The prototype ECP collaborative agreement protocol in use in the Washington State pilot project was developed using guidelines from both the American College of Obstetricians and Gynecologists and the World Health Organization in consultation with physicians and pharmacists to meet the Washington State requirements for collaborative agreements (WAC 246-863-100). The prototype ECP protocol is modified as necessary by the authorized prescriber to ensure compliance with his or her clinical standard of practice. The agreement also serves as a core component of a continuing education training program for participating pharmacists. In Washington State all protocols are submitted to and reviewed by the Washington State Board of Pharmacy.

Ongoing Collaboration Between Pharmacists and Prescribers

While physicians and pharmacists work in close proximity in many collaborative agreements, that is not always the case. Collaborative agreements have also been used in well-defined situations where very low risk is associated with drug therapy and a high need for patient access. The ECP collaborative protocol is in this latter category. Pharmacists provide ECPs to women under the agreed-upon conditions and refer women who need contraceptive services or who fall outside of their scope of the ECP agreement to the independent prescriber or another health care provider. In the first seven months of the Washington State project, over half of the participating pharmacists reported making referrals. The majority of referrals were for ongoing contraceptive care. Through referrals, the pharmacist can work to effectively link women with ongoing reproductive health care—this is particularly important when women do not currently have a health care provider.
Pharmacist Conscience Clauses
Pharmacist conscience clauses allow individual pharmacists to assert a "conscientious objection" to a drug therapy that the pharmacist finds morally troubling. The collaborative drug therapy approach to providing emergency contraception is generally not affected by these clauses because the development of collaborative agreements is completely voluntary. If a particular pharmacy has an agreement on file and is providing emergency contraceptive services, but also employs pharmacists who object to providing the service, the pharmacy should develop contingency plans to make sure that the patient’s needs are being met. These situations can be difficult, as some pharmacists may be morally opposed to even referring women to other service providers. It is important that the pharmacies address these issues, given their potential legal liability should a woman be denied access to emergency contraceptive services.

Liability Issues
Collaborative drug therapy agreements have been used in Washington State since 1979. When collaborative agreements are recognized under the State Pharmacy Practice Act, malpractice insurers automatically cover pharmacist prescribing. To date there have been no legal suits brought against pharmacists operating under prescribing protocols or their collaborating prescribers. The Center for Reproductive Law and Policy also reports that they know of no cases in which liability has been imposed against a health care provider in association with the provision of ECPs.
Expanding Access to Emergency Contraceptive Pills in Washington State: Promoting Pharmacist/Prescriber Collaborative Agreements

Introduction and Background
While efforts are underway across the country to improve women’s awareness of emergency contraceptive pills (ECPs) as a backup contraceptive method and to improve access to services, the most common ECP service delivery model (going to or calling a physician for a prescription) can present unnecessary barriers to women seeking treatment. Given that the treatment must be initiated within 72 hours of unprotected intercourse and is more effective when it is taken earlier in this time frame, establishing prescription and dispensing mechanisms that are convenient to women is crucial to their ability to use the therapy effectively.

Legislation governing pharmacy practice in Washington and other states presents a unique opportunity for increasing access to ECPs. Working under a collaborative drug therapy agreement with an independent prescriber (for example a physician), a pharmacist can prescribe ECPs directly to women who request them. For almost 20 years, Washington State physicians and pharmacists have successfully used these agreements to manage a variety of drug therapies for patients, such as pharmacokinetic drug monitoring, parenteral nutrition, anticoagulant therapy, pain drug management, immunization, and refill medication protocols.

Project Goal and Objectives
A two-year demonstration project has worked to improve women’s access to ECPs in the Puget Sound region by promoting collaborative drug therapy management agreements between independent prescribers (primarily physicians and advanced registered nurse practitioners) and pharmacists.

Specific objectives include:

- Inform retail pharmacists in the Puget Sound area about ECPs and collaborative agreement opportunities.
- Deliver and evaluate tools and training to facilitate pharmacist/prescriber collaborative agreements.
- Develop systems to link trained pharmacists with prescribers and to facilitate the establishment of collaborative agreements for ECPs.
- Conduct a 3- to 6-month promotional public awareness media campaign to reach women aged 18 to 34 with information about ECP availability through pharmacies.
- Evaluate the impact of the project on women’s access to and use of ECPs.
- Disseminate the results of the project nationally to facilitate replication in other states where regulations allow.
**Project Collaborators**
The project, funded by the David and Lucile Packard Foundation, is managed by PATH (Program for Appropriate Technology in Health), and implemented by a group of five organizations that includes PATH, the Washington State Board of Pharmacy, Washington State Pharmacists Association, University of Washington Department of Pharmacy, and Elgin DDB Needham. Collectively, the organizations have extensive experience in emergency contraception introduction, research and evaluation, pharmaceutical practice, and media and public relations campaigns. In addition to the collaborating institutions, the project is guided by an advisory committee made up of physicians and pharmacists, as well as a legislator and women’s health advocates who serve in a consultative and advisory role.

(over)

**Implementation Highlights**
Currently, approximately 130 pharmacies are participating in the project and more than 800 pharmacists have received training in all aspects of providing ECPs, including therapeutic and dispensing information, patient care issues (screening, counseling, referral, etc.), administrative issues (filing a protocol, packaging, liability, etc.), public relations, and other relevant issues.

In the first ten months of the project, 7,211 ECP prescriptions were provided to women directly from a pharmacy. Pregnancy risk can vary, depending on a variety of factors, but assuming a 10 percent pregnancy risk and 75 percent method-effectiveness rate, it is estimated that the prescriptions filled through December could have prevented as many as 540 unintended pregnancies—half of which would have resulted in abortion.

Preliminary evaluation results indicate that the majority of women receiving the service, pharmacists providing the service, and collaborating prescribers were satisfied. Over 90 percent of women who received this service said they would recommend it to others and the majority of both prescribers (95%) and pharmacists with active protocols at their work sites (86%) reported being satisfied or very satisfied with the program.