

Collaborative Drug Therapy Agreements to Promote Public Health

The Problem of Unintended Pregnancy

The number of unintended pregnancies is unacceptably high both in Washington State and in the nation as a whole. A full 40% of births in Washington State are from unintended pregnancy.[1] On a national level almost 3 million pregnancies annually are unintended and half of these are the result of contraceptive failure.[2] The consequences of unintended pregnancy to women and families can be significant:

- Approximately half of all unintended pregnancies end in abortion.
- For pregnancies carried to term, the mother is at greater risk of depression; physical abuse; not achieving her educational, financial, and career goals; and her relationship is at three times the risk of dissolution.
- The child of an unintended pregnancy is at greater risk of being born at low birth weight, dying in the first year of life, not receiving resources necessary for healthy development, and being abused or neglected.[3]
- Washington State Department of Social and Health Services estimates that the average financial cost for publicly funded care for births from unintended pregnancy is over $163 million for maternity care, labor and delivery, and medical expenses for babies' first year.[4]

Part of the Solution: Emergency Contraceptive Pills (ECPs)

Emergency contraceptive pills (ECPs) are 75% effective in *preventing* pregnancy *after* sex. ECPs are a short, high dose of ordinary birth control pills taken within 72 hours of unprotected intercourse. The most commonly used ECP formulations have both estrogen and progestin, although a progestin-only ECP is likely to become available in 1999. Recent research has shown that ECPs are more effective the sooner they are taken, with the highest efficacy in the first 24 hours.[5] Widespread use of and easy access to ECPs can significantly reduce unintended pregnancy.[2,6] Although ECP regimens have been used for over 20 years, a 1997 study found that only 10% of health care providers routinely discuss emergency contraception, and it is infrequently prescribed.[7]

ECP Mechanism of Action and Safety

Several studies have shown that ECPs can inhibit or delay ovulation when given before or at the time of ovulation.[8,9,10] Minor changes in histologic and biochemical features of the endometrium occur when ECPs are given after ovulation. These effects may inhibit implantation.[11]

Organizations that have endorsed ECPs as safe and effective include the World Health Organization, the International Planned Parenthood Federation, the United

States Food and Drug Administration, and the American College of Obstetricians and Gynecologists.[12,13,14]

Washington State's Unique Approach to Increasing ECP Access

The Emergency Contraception Collaborative Agreement Pilot Project is an innovative two-year (July 1997 to June 1999) pilot program in Washington State to increase women's awareness of and access to ECPs by making this contraceptive method available directly from a pharmacist.

Washington State pharmacists participating in the pilot project receive continuing education training in all aspects of ECP provision. Pharmacists screen women and routinely provide counseling on ECP use as well as ongoing contraception to women. Pharmacists also make appropriate referrals for contraceptive care, sexually transmitted disease diagnosis, and treatment of sexual abuse, and they review issues necessary for informed consent with prospective ECP users.

In the ten months following the Project's public launch on February 25,1998, area pharmacists at 128 participating pharmacies wrote and filled 7,211 ECP prescriptions. The number of prescriptions can be used to roughly estimate the number of unintended pregnancies and abortions prevented through the program. Assuming a 10% pregnancy risk and 75% method effectiveness, ECP prescriptions written and filled by pharmacists theoretically have prevented 540 unintended pregnancies. In Washington State approximately half of unintended pregnancies end in abortion, so in ten months the program also has prevented approximately 270 abortions.

ECP Prescribing Through Collaborative Drug Therapy Agreements

Pharmacists are able to prescribe 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. The agreement is based on a prescriptive protocol agreed to by the licensed prescriber and the pharmacist. Once the agreement is in place, the pharmacist can provide the therapy to any person who presents with a need for it and who meets the screening criteria outlined in the protocol. These agreements afford an excellent opportunity for pharmacists to collaborate with other reproductive health care providers to meet the needs of women.

The medical community has shown support for the use of collaborative agreements for prescribing ECPs, and many physicians are involved in ECP collaborative agreements. The Washington State Medical Association passed a resolution in support of the pilot project, with the following opening statement: "RESOLVED, that the Washington State Medical Association supports the pilot program that allows retail pharmacists in Washington to dispense emergency contraceptives directly to patients under a prescriptive protocol, with a local physician advisor."

Collaborative agreements have a long history in Washington State. Authorization for pharmacists to prescribe developed out of a 1979 revision to the Pharmacy Practice Act (RCW 18.64.011). Final regulations were put forth by the Board of Pharmacy in 1981 (WAC 246-863-109). Collaborative drug therapy agreements

have been used successfully for a number of therapies, including adult immunizations, pain drug therapy management, and, most recently, ECPs. Under the agreement, the licensed prescriber has primary responsibility for authorizing protocols and reviewing pharmacist conduct under the protocol, while the State Board of Pharmacy has the role of ensuring that prescribing protocols are properly prepared and filed, and that pharmacists are practicing under the guidelines described in the protocol.[15]

Benefits of Pharmacy Access to ECPs

For licensed prescribers, working with pharmacists to provide ECPs directly through pharmacies offers a number of advantages including:

- improved patient access to ECPs;
- reduction in emergency clinic visits;
- decreased health care costs;
- increased collaboration among health care providers.

For women, pharmacies can provide one more avenue of access to ECPs, enabling them to initiate use early and within the critical 72-hour window. The preliminary user survey data, as well as reports from pharmacies, indicate that many women go to the pharmacy on weekends or after normal business hours for their ECP prescriptions, and that they value this accessibility. Preliminary evaluation results also indicate that women receiving the service are satisfied with the quality of care they have received. A high percentage of survey respondents said they understood the written and verbal information given to them by the pharmacist, they had sufficient opportunity to ask questions, and they felt they were treated with respect. Women also felt satisfied with the ECP use instructions they received and with the counseling provided regarding ongoing contraceptive care.

A cost-impact model using Washington State cost estimates and the number of women served in the project showed that emergency contraception obtained from a pharmacist prevented unintended pregnancies and was cost saving. In modeling the private payer cost impact, the cost savings were without exception overwhelmingly positive, even when employing highly conservative assumptions. When the base case assumptions were used—that is, an ECP effectiveness rate of 74% and a probability of conception for any given act of unprotected intercourse of 7.2%—the cost impact was positive for all the private and public payer models. As the progestin-only regimen has higher rates of effectiveness than the combined regimen, more cost savings may be expected once that product is available in a format specifically packaged and labeled for emergency contraception.

Referral for Ongoing Care

At seven months of service, a survey of collaborating licensed prescribers and participating pharmacists demonstrated a high level of satisfaction: 92.3% of prescribers and 84.0% of pharmacists were satisfied with the program. The survey of pharmacists also revealed that they had made over 500 referrals to other health providers, over half of which were for ongoing contraceptive care. User survey results show that many women who received ECPs directly from a pharmacist did not have a regular health care provider. Thus, pharmacists can play a critical role in bringing women into the health care system.

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Emergency Contraception Collaborative Agreement Pilot Project, Collaborating Institutions

• Program for Appropriate Technology in Health (PATH) • University of Washington Department of Pharmacy • Washington State Pharmacists Association • Washington State Board of Pharmacy • Elgin/DDB

Project Advisory Committee

• Maxine Hayes, M.D., Assistant Secretary, Community and Family Health, Washington State Department of Health • Jack Leversee, M.D., Past President, King County Academy of Family Practice Physicians • Terry Rogers, M.D. • The Honorable Helen Sommers, State Representative • Lisa Stone, Executive Director, Northwest Women's Law Center • Dianne White, R.Ph. • Mike Kreidler, O.D., Regional Director, Department of Health and Human Services • Henry Ziegler, M.D., Prevention Division Director, Seattle-King County Department of Public Health

For more information contact Jane Hutchings at PATH
Telephone: 206-285-3500/Fax: 206-285-6619

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