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SPECIAL REPORT

Increasing Access to Emergency Contraception Through Community Pharmacies: Lessons from Washington State

By Jacqueline S. Gardner, Jane Hutchings, Timothy S. Fuller and Don Downing

In 1997, the U.S. Food and Drug Administration endorsed the use of a combination estrogen and progestin oral contraceptive for emergency postcoital contraception.¹ In 1998, the agency approved the first dedicated emergency contraceptive product for use in the United States, and in 1999 it approved the first progestin-only emergency contraceptive pill.² Despite emergency contraception's safety, effectiveness and unique ability to reduce unintended pregnancy, it has been vastly underused. One study conducted in 1997 found that only one in 10 health professionals routinely discussed emergency contraception with their clients, and that 41% of Americans were completely unaware of its existence.³

The Institute of Medicine advocates an aggressive effort to reduce the number of unintended pregnancies, by increasing access to contraceptive information and services and by broadening the range of health care professionals and institutions that promote and provide contraceptive services.⁴ In response to this mandate, five organizations in Washington State—the nonprofit organization Program for Appropriate Technology in Health (PATH), the Washington State Pharmacists Association, the University of Washington Department of Pharmacy, the Washington State Board of Pharmacy and the Seattle office of the advertising firm DDB Worldwide Communications Group, Inc.—initiated a pilot project in July 1997 to reduce unintended pregnancy in Washington by increasing women's access to and the public's awareness of emergency contraception.⁵ The pilot project was conducted from February 1998 to June 1999. Over the course of the project, women received 11,969 prescriptions for emergency contraceptive pills from pharmacists at 130 pharmacies. This article describes the 16-month pilot project and ongoing project activities.

ELEMENTS OF THE PROJECT

Collaborative Drug Therapy Agreements

The foundation of the project was the design and implementation of collaborative drug

therapy agreements between pharmacists and independent prescribers— either physicians or advanced registered nurse practitioners. These agreements authorize pharmacists to provide emergency contraception directly to women without their having to make a prior visit or consult with a prescriber. The written agreements define drug initiation, modification, monitoring, continuation and documentation requirements that are to be performed only as agreed upon by the authorizing prescriber and the pharmacist.¹

In Washington State, the collaborative drug therapy agreements are filed with the Board of Pharmacy and must be renewed at least biannually. This mechanism has been used previously in Washington State to broaden pharmacists' role in providing access to immunizations, asthma therapy, diabetes and cholesterol screening and chronic disease management. $\frac{6}{2}$

Protocol and Consent Process

The emergency contraception protocol used in this project was developed in consultation with physicians and pharmacists, and based on guidelines from the American College of Obstetricians and Gynecologists,⁷ Planned Parenthood Federation of America and the World Health Organization.⁸ The protocol and the consent process incorporate screening to rule out established pregnancy, to ascertain suitability of emergency contraception treatment and to identify counseling and referral needs. The protocol also allows for prescribing emergency contraception in advance of need¹ and requires that the authorizing prescriber and the pharmacist perform a quarterly review of prescribing decisions. The agreement is signed jointly by one prescriber and one pharmacist and applies to all women who request services according to the protocol. Any trained and certified pharmacist who works under the supervision of the signing pharmacist also may prescribe under the established protocol. A pharmacy therefore may have several qualified emergency contraception providers on its staff, including certified student interns.

Project Advisory Committee

An advisory committee was formed of physicians, pharmacists, attorneys, politicians and administrators of state and local health jurisdictions to provide direction to the project.[§] Committee members also served as spokespeople for the project with media and other constituents. The group met approximately quarterly during the pilot project, and members continue to be advocates for pharmacist-provided emergency contraception.

Pharmacist Training and Certification

To provide pharmacists with appropriate information and guidelines, the project collaborators designed a standardized continuing education program that addresses emergency contraceptive pill regimens, assessment and prescribing parameters, and necessary counseling skills. The group also produced a comprehensive training manual. Since the initiation of the project, the training program has been streamlined: The didactic portion has been published as a report, ** and pharmacists complete a course of home study online prior to attending a group practicum session.

The practicum session is devoted to demonstrating and practicing role-play situations

that pharmacists have encountered in the process of providing emergency contraception. These include, for example, the basics of the counseling session, calming anxious women, interacting with parents who learn that their daughters have been treated, helping women choose follow-on contraceptive methods and what women should do if they miss the second pill in the regimen. The group session lasts three hours. For the combined didactic home study and group practicum session, pharmacists receive five hours of continuing education credits. Students in Washington's two pharmacy schools can receive the same training in elective courses.

As of May 2001, more than 1,500 pharmacists and pharmacy students had been trained and certified to provide emergency contraception. At any given time, the service is provided in approximately 180 pharmacies in Washington, including multiple locations of nine retail or grocery pharmacy chains.^{±±}

PROJECT IMPLEMENTATION

Outreach and Media Coverage

To launch the pilot project, collaborators conducted a three-month media campaign to increase awareness of emergency contraception and of the national emergency contraception hotline (1-888-NOT-2-LATE). Public relations and promotional activities were implemented to reach women aged 18-34. While this age-group was chosen to avoid controversy over targeting adolescents, placement of promotional pieces was sufficiently broad—for example on public buses and the radio—that younger women were likely to have received the message as well.

Beginning in February 1998, the campaign ran radio and print advertisements in alternative weeklies and college newspapers for 12 weeks. Approximately \$145,000 was spent on these advertisements. Because the advertisements were of a public-service nature, the project was able to leverage additional media time at no cost. In addition, an intensive media relations campaign was conducted with local and national consumer and trade publications, and a follow-up effort was conducted in the summer of 1998 to announce the project's preliminary results.

News of the pilot project appeared throughout the U.S. print and television media: During the first year of the project, more than 120 news stories appeared on television programs throughout the United States, and hundreds more appeared in print and aired on the radio. Six wire services carried reports on the project.

The success of the Seattle media campaign in increasing awareness of the availability of emergency contraception and the need to use it within 72 hours of unprotected intercourse has been documented elsewhere.⁹ Calls from Washington State to the national hotline increased 10-fold, to an average of 1,160 per month after the project launch, compared with 110 per month before the launch. Currently, the rate is about 19-20 per month. There are a few possible reasons for this reduction in call volume. One reason could be that more women are using the Internet to access information about the availability of emergency contraception on the national emergency contraception hotline's Web site, NOT-2-LATE.com (http://ec.princeton.edu; city-specific "hits" to the site are not available). It also is possible that calls to the hotline from Washington State declined because information about the availability of emergency contraception in pharmacies has spread effectively through word of mouth

and through periodic press coverage. Another possibility could be that because targeted media messages have not continued and participating pharmacies have not increased in-store advertising of emergency contraception services, information about the hotline is not sustained in the public's mind.

Support for the Project

Various institutions and provider groups provided support to the project's objectives. In October 1998, the Washington State Medical Association passed a resolution to "support the pilot program that allows retail pharmacists in Washington to dispense emergency contraceptives directly to clients under a prescriptive protocol, with a local physician advisor" and "to publicize the existence of this particular pilot program."¹⁰ In November 1998, the American Medical Women's Association passed a resolution "advocating programs that provide improved access to emergency contraception pills for women through collaborative agreements, especially for after-hours need (including further study of programs such as those that enable protocols for pharmacists to directly prescribe emergency contraception)."¹¹ Since the completion of the pilot project, the American Pharmaceutical Association House of Delegates passed a resolution in March 2000 that "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."¹²^{±1}

Many prescribers publicized the availability of emergency contraceptive pills directly through contact with their clients and indirectly through messages on their after-hours answering machines that referred callers to a pharmacy for emergency contraception. Planned Parenthood affiliates, county health department family planning clinics and other women's clinics uniformly referred their clients when participating pharmacies were more readily accessible.

Soliciting Feedback

During the pilot project, surveys were conducted to solicit feedback from women who received emergency contraception and from prescribers and pharmacists who had entered into collaborative prescribing agreements. When prescribing emergency contraceptive pills, pharmacists provided their clients with a brochure containing instructions for emergency contraceptive pill use, discussed the effects and side effects of emergency contraceptive pills and provided information about preventing pregnancy in the future. An anonymous, postage-paid survey was attached to the brochure to solicit information about clients' personal characteristics, experiences and satisfaction with the service and about their access to emergency contraception. Women were asked to tear off the survey from the emergency contraception information brochure, complete it and mail it to the coordinating center. Although the response rate was very low, this feedback guided the pharmacist training. For example, women reported that they had not been well-served in the area of counseling for effective, ongoing contraceptive use. As a result of this feedback, the training programs were modified to place greater emphasis on this information.

A survey also was conducted of all prescribers who had entered into emergency contraception collaborative prescribing agreements with pharmacists during the first

six months of the project and all pharmacists who had completed the standardized emergency contraception training program provided by the Washington State Pharmacists Association. The survey was constructed to obtain information about participants' satisfaction with the program, about participants' characteristics, including the training they received, and their service delivery. Results of this survey have been published elsewhere.¹³

Briefly, half of the pharmacists and prescribers responded to the survey. Of these, 92% of both prescriber and pharmacist respondents who had emergency contraception prescribing experience reported being "satisfied" or "very satisfied" with their emergency contraception agreements. There was no difference between physicians and advanced registered nurse practitioners in the level of satisfaction with the agreements. Pharmacists working in retail chain pharmacies expressed higher rates of satisfaction with the agreements than did independent pharmacists. Two-thirds of pharmacists reported referring at least one patient for further care.

On a quarterly basis, participating pharmacies reported the number of prescriptions they had initiated during the quarter. Since completion of the pilot project in June 1999, that reporting cycle has been extended to semiannual reporting. A broadcast fax system has been developed that requests from each participating pharmacy the number of women provided emergency contraceptive pills in the previous six-month period, with telephone follow-up of nonrespondents. From February 1998 through December 2000, Washington State pharmacists reported having served 28,649 women. During the period from July to December 2000, more than 1,000 emergency contraception prescriptions were initiated by pharmacists per month.

Cost of Emergency Contraceptive Pills

Clients who received emergency contraceptive pills paid cash for the service. The price averages between \$30 and \$40, which includes the emergency contraceptive pills, an antiemetic to prevent nausea and vomiting, and the pharmacist's time in assessing, counseling and documenting the interaction. Medicaid coverage was initiated for eligible women late in the project. One private insurer has begun to authorize coverage of emergency contraceptive pills provided by pharmacists.

Despite the absence of third-party payment for emergency contraceptive pills, thousands of women have used the service. It is likely, however, that women who could not afford the fee did not seek emergency contraceptive pills from their pharmacists. While there is considerable national attention paid to state and federal initiatives to include contraceptives in employers' health coverage, these initiatives do not include the cost of screening, counseling and referral by pharmacists. Consequently, women who seek emergency contraception continue to pay out of pocket for the prescription.

Costs and outcomes of the decision to obtain emergency contraceptive pills from a pharmacy were modeled. The results of this analysis showed the provision of emergency contraceptive pills by a pharmacist to be cost-saving under all assumptions for both public and private payers. $\frac{14}{2}$

Political Opposition

The national media have reported that some pharmacists resist providing emergency contraception.¹⁵ Though such resistance has periodically influenced the development of "conscience clause" proposals in state legislatures, the pilot project did not encounter such resistance. In addition, the public rarely has expressed opposition to pharmacists' provision of emergency contraceptive pills in Washington State.

However, pharmacists practicing in small towns or in rural areas of the state often report being sensitive to a conservatism in the communities that makes them reluctant to advertise their provision of emergency contraceptive pills, either within the stores or more broadly. This reluctance appears to have had an impact on women's awareness of the availability of emergency contraceptive pills in rural areas: The volume of prescriptions from many of the rural pharmacies has been low, despite high rates of unintended pregnancy in those areas. In recent months, recruitment of emergency contraception prescribers and pharmacists to serve as spokespeople from these areas has been enhanced to help encourage and support pharmacists who wish to become involved, but who are concerned about the community's potential to react negatively to their association with emergency contraception. Because pharmacists nurture strong collegial relationships with prescribers for their day-to-day business, they are careful not to initiate activities that might compromise those relationships. Therefore, prescribers who take a proactive role in encouraging pharmacists' involvement in providing education and services associated with emergency contraception and in advocating this role with the community can have a strong impact upon increasing the women's access to emergency contraception.

Impact on Pregnancy and Abortion Rates

If the increased accessibility of emergency contraception reduces unintended pregnancy, there should be evidence of reduced pregnancy and abortion rates. To be sure, abortions in Washington reached the lowest level in two decades, dropping by 5% from 1997 to 1998, and teenage pregnancy rates were 7% lower during that period.¹⁶ However, the national abortion rates also were declining during this period, reaching their lowest levels since 1978.¹⁷ In 1999, both pregnancy rates and rates of induced abortion increased slightly in Washington State, although still not approaching the higher rates that were seen before the emergency contraception project began.¹⁸ Further, the earlier decline in abortion rates, particularly among rural women, has been associated with a pattern of decline in the number of abortion providers over the past decade.¹⁹

Therefore, before one can make a definitive statement about whether improved access to emergency contraception can reduce pregnancy and abortion rates, it is necessary to observe a longer period than currently is possible, as well as to conduct research that controls for all potential confounding variables. In the meantime, however, models that incorporate assumptions of pregnancies averted continue to show that women's access to emergency contraception can reduce unintended pregnancies and abortions.²⁰

OTHER PROGRAMS

Other states and countries have used Washington's experience as a practice model and an inspiration in implementing programs ranging from pilot projects to legislative

mandates. California and Alaska have initiated pilot programs. In 2000, the Parliament of the United Kingdom authorized pharmacists to prescribe emergency contraception under protocol with physicians.²¹ In October 2000, the Premier of the Canadian province of British Columbia began to permit pharmacists to prescribe emergency contraception without requiring that they establish collaborative protocols with physicians,²² an action that was signed into law by the Parliament on April 2, 2001.

ONGOING ACTIVITIES

Pharmacy-based emergency contraception services are convenient for women, increase the chances that women will use the regimen within the 72-hour administration window and provide access to women who lack another source of medical care. As a result of the pilot project, provision of emergency contraceptive pills has become a standard component of practice for many pharmacists throughout Washington.

Although the pilot project's official activities have ended, pharmacists in Washington continue to participate in emergency contraception training programs, prescribers are signing new protocols and women are seeking and obtaining emergency contraception services in pharmacies. Both of the state's schools of pharmacy now include emergency contraception prescribing, counseling and referral in their curricula. Pharmacists' provision of emergency contraceptive pills has become a standard practice in many Washington pharmacies, with more than 180 collaborative drug therapy protocols in place. At the completion of the pilot project, collaborators next focused on the expansion of pharmacist-provided emergency contraception services into rural areas of Washington, with project funding from the Department of Social and Health Services. This project will end in July 2001.

Increasing access to emergency contraception through community-based pharmacists, in collaboration with physicians and advanced registered nurse practitioners, is a public health measure that has been shown to be acceptable to everyone involved. Similar programs could be implemented in the other 28 states that currently have pharmacy practice acts with a provision for collaborative drug therapy agreements.

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<u>*</u>Members of the collaborative project team included Rod Shafer, CEO, Washington State Pharmacists Association; Stephanie Abbott, pharmacist, Kelley-Ross Pharmacy; Pamela Long, account supervisor, DDB Worldwide Communications; Arlene Fairfield, senior vice president, DDB Issues and Advocacy, DDB Seattle; and Don Williams, executive director, Washington State Board of Pharmacy.

In addition to Washington, 28 other states have collaborative agreements: Arizona, Arkansas, California, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, South Carolina, South Dakota, Texas, Vermont, Virginia, Wisconsin and Wyoming.

During the pilot project, there was very little indication of a demand for prescription in advance of need. Pharmacists currently are reporting anecdotally that they are beginning to receive requests for advance prescription.

SThe Project Advisory Committee included Maxine Hayes, state health officer, Washington State Department of Health; Terry R. Rogers, president, Rogers, Ltd.; Jack Leversee, past president, King County Academy of Family Physicians; SuAnn Bond, program manager, Immunex Corp.; State Representative Helen Sommers, 36th District, Washington State Legislature; Lisa Stone, executive director, Northwest Women's Law Center; Dianne White, immediate past president, Washington State Pharmacists Association; Mike Kreidler, Washington State Insurance Commissioner; Henry Ziegler, director, Prevention Division, Seattle-King County Department of Health; and U.S. Representative Jay Inslee, First Congressional District, U.S. House of Representatives.

** *Emergency Contraception: The Pharmacist's Role,* by the American Pharmaceutical Association, can be found on the association's Web site at http://www.aphanet.org. It also is available as a home study

continuing education program from the Washington State Pharmacists Association, at http://www.pharmcare.org. The collaborative protocol and the informed consent document used by Washington State pharmacists, as well as information about management of requests from minors and victims of abuse, also are on the Washington State Pharmacists Association Web site.

[★] Periodically, services may be suspended at a particular site when a certified pharmacist retires or is transferred. New certification programs are ongoing, new pharmacy sites are added regularly and suspended sites are being reactivated when new staff are certified.

Lin July 1999, the American Medical Association House of Delegates passed a more limited resolution in support of emergency contraception to "improve public health education on all forms of birth control, including emergency contraception, by working with appropriate specialty societies and other organizations." (Source: American Medical Association House of Delegates, Resolution 116 (I-99).)

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