

Provision of emergency contraceptives by pharmacists

British Columbia experience a template for other provinces

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On December 1, 2000, specially trained pharmacists in British Columbia became the first in Canada to be formally granted independent prescriptive authority for emergency contraceptives (ECs). The provincial government implemented this precedent-setting health policy initiative to reduce barriers to access for this time-sensitive birth control option. Since legislation to enhance the scope of pharmacy practice was enacted three years ago, the provision of ECs to women at risk of an unwanted pregnancy has increased substantially. In the process, pharmacists have gained increasing recognition of their role as collaborative health care professionals.

This article describes the change in BC health policy that granted pharmacists independent prescriptive authority, explains how pharmacist prescribing relates to Canadian federal and provincial drug schedules, and describes the impact of the expanded role of pharmacists on EC utilization. It also explores issues that remain to be considered should one or more of the EC agents be transferred to non-prescription status.

Background

The pharmacy profession has been evolving rapidly toward a more patient-oriented type of practice. Opportunities are increasing for pharmacists to improve patient outcomes and quality of life through their expanded roles as drug therapy providers. As primary health care practitioners, pharmacists often represent the most accessible point of contact within the health care system. Innovative pharmacy practice models are now being developed to capitalize on the drug therapy education and expertise of pharmacists.

Washington is one of several American states that has developed collaborative agreements between physicians and pharmacists to permit pharmacists to monitor, adjust, or prescribe drug therapy. The aim of these agreements is to improve patient care through "increasing access to primary health care in a cost-effective manner, reducing drug-related problems and improving therapeutic outcomes, and using resources most effectively."¹ In Canada, the Canadian Society of Hospital Pharmacists has developed a statement on pharmacist prescribing, supported by extensive background information, to encourage expansion of collaborative prescribing authority in organized health care settings.^{2,3} In addition, some Alberta pharmacists are now exploring multidisciplinary and collaborative approaches to prescribing.⁴

ECs are easy to use, have a good safety profile, and are an effective method of reducing the risks associated with unintended pregnancy.^{5,6,7} A recent study by the World Health Organization supported the idea that the earlier an EC is taken after unprotected intercourse, the more effective it is in preventing pregnancy.⁸ Because the effectiveness of EC is time-dependent, it is critical to establish mechanisms of EC provision that are convenient and that minimize barriers to access.

Community pharmacists are ideally positioned to improve timely access to ECs,⁹ as they are:

- Located in urban, rural, and remote settings
- Often accessible weeknights, weekends, and holidays (when physician offices and clinics are closed)
- Respected and highly educated health care professionals
- Experienced in counselling on reproductive health issues.

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For many women who do not have a regular physician, access to ECs through a pharmacy avoids the delay in setting up an appointment with a physician.¹⁰ Some women may also find visiting a pharmacy less intimidating than visiting a physician's office, and they may appreciate being able to drop in at a convenient time.⁸

Introducing prescriptive authority

In January 1999, the director of PharmaCare (the BC Ministry of Health's third-party prescription payment plan) approached the College of Pharmacists of British Columbia and the British Columbia Pharmacy Association (BCPhA) to discuss the development of a program through which pharmacists could prescribe ECs directly. Late 1999 was considered a reasonable target date for implementation.

The College and the BCPhA determined that the success or failure of a pharmacy-based EC program would depend on the answers to five critical questions:

- Does prescriptive authority fall naturally within pharmacists' abilities and practices?
- Is there a need for the service and a favourable sociopolitical environment to support it?
- Will the regulations let us do it?
- Is it economically worthwhile and feasible?
- Can we get the needed support from other health professionals? If not, where will the opposition come from and how will we deal with it?

The College began researching different regulatory approaches and designing a survey to obtain feedback from BC pharmacists. Concurrently, BCPhA committed to developing and administering an EC training program and investigating economic viability of the program. Jointly, the two organizations began networking with stakeholders and advocacy groups in the reproductive health area. They also visited the Washington State Board of Pharmacy to explore regulatory and training issues, as identified by the pilot project then underway. Organizations such as the Minister's Advisory Council on Women's Health and the

TWO FORMS OF EC

Yuzpe method	Two types of hormonal ECs are used in Canada. The Yuzpe regimen is the most commonly administered form. Two doses of a combination estrogen-progestin product (Ovral) (each dose consisting of 0.1 mg ethinyl estradiol and 0.5 mg levonorgestrel) are taken 12 hours apart.
Plan B	With the progestin-only product (Plan B, containing levonorgestrel 0.75 mg per tablet), a single dose of two tablets is taken as soon as possible after unprotected intercourse. ¹¹

While ECs traditionally have been used up to 72 hours after unprotected sexual intercourse, recent research suggests that both hormonal methods are effective when administered up to 120 hours after unprotected intercourse or contraceptive failure.^{12,13}

Planned Parenthood Association of British Columbia expressed support for the initiative.

Over several months, the two pharmacy organizations determined that the answers to the five pivotal questions were all positive. By the summer of 1999, no opposition to the EC initiative had surfaced, and individual physicians were generally supportive. In September 1999, the College of Pharmacists of British Columbia distributed EC briefing notes and a survey to determine pharmacists' interest in providing ECs after specialized training. Almost 600 community pharmacists immediately expressed interest in participating. Many pharmacists throughout the province also expressed an interest in receiving additional training, so that they could themselves become trainers and teach other pharmacists in their respective regions.

CONSENSUS CONFERENCE ON CONTRACEPTION

The impetus to explore options for prescriptive authority for ECs began in November 1998 when the Society of Obstetricians and Gynaecologists of Canada (SOGC), following recommendations of the 1998 Canadian Consensus Conference on Contraception,⁵ endorsed the concept of expanding access to emergency postcoital contraception.¹⁴ This endorsement recognized the rising rates of termination of pregnancy in Canada, the compelling reasons to reduce the incidence of unwanted pregnancies, and the difficulties of timely provision of physician-prescribed ECs. The SOGC motion stated that ECs should be made available without prescription through pharmacies and other sources of health care.

Although ECs had been prescribed for more than

25 years by family physicians, gynecologists, family planning clinics, and emergency department physicians,¹⁵ over 14,000 pregnancies were terminated with an abortion in British Columbia in 1998,¹⁶ which represented 23% of all pregnancies and more than 54% of pregnancies in women 15 to 19 years of age. These high rates of abortion substantiated concern that unintended pregnancies and subsequent abortions constituted a major public health issue in the province. The College of Pharmacists of British Columbia was one of the first licensing bodies in Canada to support the SOGC motion and actively explore professional practice policies and controls to enable pharmacists to initiate EC therapy.

Introducing Schedule IV

The Council of the College submitted a resolution for Cabinet approval proposing changes to the Drug Schedules Regulations to permit pharmacist-prescribed ECs in late summer 1999. Two potential legislative routes were investigated simultaneously:

1. The first was to develop a mechanism for dependent prescriptive authority, similar to the model of collaborative agreements for drug therapy used in Washington State. With this mechanism, it was proposed that one or more physicians in an appropriate position, such as the provincial medical officer or delegate, would sign a standardized protocol for pharmacists who had completed the EC education program, and the pharmacists would provide periodic summary reports to the delegating physician.
2. The second option was to have the provincial government grant to pharmacists the right to prescribe drugs and to limit that authority to ECs. A precedent for the latter mechanism was the authority previously granted to optometrists and midwives for prescription of specific medications used in their professions. It was proposed that the BC Ministry of Health amend the provincial drug schedules by adding a new drug category, which would contain EC products only, and permitting pharmacists to prescribe these drugs.

In September 1999, the Council of the College adopted guidelines for the new Schedule IV, specifying that pharmacists must complete an approved training program before prescribing ECs and that they must maintain appropriate documentation. In November 1999, the Council forwarded the Schedule IV resolution and accompanying guidelines to the Ministry of Health for consideration.

Steering committee

At that time, discussions on a comprehensive assessment of proposed policy's impact were initiated among the College of Pharmacists of British Columbia, the BCPhA, and the Collaboration for Outcomes Research and

Evaluation group within the Faculty of Pharmaceutical Sciences, University of British Columbia. A pivotal component of this outcomes evaluation is the high-profile steering committee, which is composed of key stakeholders in the area of reproductive health in the province. Committee members include senior government policy makers (the provincial medical officer, the senior advisor in women's health, and the senior policy analyst in women's health), women's health care providers (the president of the British Columbia's Women's Hospital & Health Centre and the program director of the Comprehensive Abortion and Reproductive Education Program), advocacy groups (the BC Centre of Excellence for Women's Health and Planned Parenthood Association of British Columbia), the deputy registrar of the College of Pharmacists of British Columbia, and the principal investigator of the Washington State EC program.

Certification

BC pharmacists began certification training in November 1999, using a modified version of the Washington State training manual.¹⁷ A form was designed to obtain the patient's informed consent for the EC interview protocol, and to capture data:

- Date of the last menstrual period
- Time of unprotected intercourse
- Type of birth control failure or whether no method was used
- EC agent and the date dispensed
- Pharmacy code
- Whether an antiemetic was provided
- Type of referrals to health care professionals (e.g., for sexually transmitted infections or regular birth control).

As a component of the training, pharmacists learned how to complete a collaborative drug therapy agreement and how to comply with the feedback mechanism to the licensed prescriber.

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THE WASHINGTON STATE EXAMPLE

Washington State became the first jurisdiction to allow specially trained pharmacists to prescribe ECs. The pharmacy legislation originally enacted in that state in 1979¹ enables an individual pharmacist to develop collaborative drug therapy agreements with a particular health care professional authorized to independently write prescriptions. Each agreement requires a specific prescribing protocol detailing the drugs involved, the decision criteria for prescribing, the method of documentation, and plans for feedback to the licensed practitioner.¹⁰ The agreements are reviewed and filed by the Washington State Board of Pharmacy and are to be renewed every two years.

In a 16-month pilot project, pharmacists in 130 phar-

macies dispensed 11,969 EC prescriptions directly to women requesting these agents.¹⁸ Because baseline data on physician-prescribed ECs were not available, it is difficult to assess the impact of this pilot project on EC utilization, but the data do provide some support for the notion that expanded access through pharmacist-initiated prescribing can increase the utilization of these postcoital agents.

Overwhelming endorsement of the initiative by health care professionals, advocacy groups, and EC users and lack of opposition to pharmacists' provision of ECs in Washington State were important considerations when British Columbia began exploring innovative options to expand access in that province.

Amendment passed

Despite active support from the health minister and the minister of women's equality, bureaucratic delays and concerns of the College of Physicians and Surgeons of British Columbia regarding liability issues associated with delegated prescribing stalled further progress for another 11 months.

Then, on October 26, 2000, with almost no warning, the BC premier, Ujjal Dosanjh, announced the regulatory amendment had been passed by the Lieutenant Governor through an Order in Council. Commencing December 1, 2000, trained, certified pharmacists had independent prescriptive authority to provide ECs to women without a prescription from a physician. On April 2, 2001, the regulatory change was granted statutory authority by the provincial legislature.

The reasons for the premier's sudden legislative action were likely multidimensional and political, as an election was imminent. During his speech on October 26, 2000, the premier stated: "There is no reason any woman in British Columbia should face an unwanted pregnancy when there is a medically safe and effective alternative. We are acting now to prevent the personal and social costs of unwanted pregnancies." He went on to say, "Too many women for too long have been denied the use of emergency contraception pills because they couldn't get them when they needed them."

While the motivation to implement this health initiative

may have been political, the choice of the specific amendment to the drug schedules reflected the systematic and meticulous legal and regulatory preparatory work by the College of Pharmacists of British Columbia, which succeeded in making the case for acknowledging pharmacists as "practitioners" who could prescribe. The fact that more than 800 community pharmacists were already certified to prescribe ECs expedited the five-week start-up time between the announcement and implementation on December 1, 2000.

Assessment

In the first two years of the pharmacist-initiated EC program in British Columbia, more than 1500 certified pharmacists from nearly 400 community pharmacies in all regions of the province provided a total of more than 13,200 EC prescriptions.¹⁹ In accordance with the informed consent protocol, the pharmacists provided women with information on the relative effectiveness, side effects, and cost of the two EC regimens. On the basis of this information, more than 60% of the women chose the levonorgestrel-only agent.¹⁹

Pharmacists also routinely discussed regular methods of birth control and criteria that might put the woman at risk for sexually transmitted infections and offered referrals to health care providers when necessary. More than 55% of the ECs were provided on weeknights, weekends, and holidays, when most physician offices and clinics were

REGULATORY FRAMEWORK

The federal and provincial regulatory framework in Canada allows for pharmacist prescribing. The regulatory basis for pharmacist prescribing of ECs, summarized in Table 1, depends on designating pharmacists as practitioners specifically for this purpose.

At the federal level, the Therapeutic Products Directorate within Health Canada oversees the Food and Drugs Act, which approves drugs for sale in Canada.²⁰ The federal government determines whether a drug should be a prescription drug (Schedule F)²¹ or a non-prescription drug. Prescription drugs require a prescription by an authorized "practitioner," as defined by provincial legislation.

In addition, each province determines the conditions for the sale of non-prescription drugs, on the basis of recommendations by the National Drug Scheduling Advisory Committee (NDSAC). The National Association of Pharmacy Regulatory Authorities (NAPRA) formed NDSAC in August, 1995, to advise the provincial pharmacy regulatory authorities on matters relating to the placement of drugs within a national drug scheduling model.

All provinces have a prescription category (Schedule I) and three categories for non-prescription drugs (Schedules II, III, IV):²²

Schedule I (prescription) drugs require a prescription for sale and are provided to the public by a pharmacist following the diagnosis and professional intervention of a practitioner. The sale is controlled in a regulated environment, as defined by provincial pharmacy legislation.

Schedule II (behind-the-counter) drugs require professional intervention from the pharmacist at the point of sale and must be held in an area of the pharmacy without public access or opportunity for self-selection by patients.

Schedule III (over-the-counter) drugs do not require direct professional intervention, but a pharmacist must be available to provide advice if requested.

Unscheduled drugs may be sold from any retail outlet by a non-pharmacist.

Quebec and Saskatchewan adopted the BC independent prescriptive authority model for ECs by making provincial legislative changes involving the definition of a "practitioner." These two provinces initiated EC prescribing in December 2001 and September 2003, respectively. A successful pilot EC program using a collaborative physician-pharmacist agreement model was conducted in three areas of Toronto, Ontario, from June 2001 to November 2002.²³

TABLE 1 — Regulatory basis for prescribing by pharmacists in Canada

Level of government	Description
Federal	The federal <i>Food and Drugs Regulations, Part C, Drugs</i> ²⁰ states that only a practitioner may prescribe Schedule F drugs, and that <i>provinces</i> determine who can be a practitioner. For the purpose of these Regulations, a practitioner is "a person authorized by the law of a province of Canada to treat patients with any drug listed or described in Schedule F to the Regulations."
Provincial (British Columbia)	In British Columbia, the <i>Pharmacists, Pharmacy Operations and Drug Scheduling Act</i> ²⁴ defines a practitioner as "a person authorized to practice medicine, dentistry, podiatry, veterinary medicine or a prescribed health care profession in which a practitioner of that profession is authorized to prescribe drugs or devices." <p>To be granted prescriptive authority, BC pharmacists had to be designated as practitioners under provincial law. In October 2000, the Lieutenant Governor, with the advice and consent of the Executive Council of the BC legislature, amended the <i>Prescribed Health Care Profession Regulation</i>²⁵ with an Order in Council that added the following: "Pharmacy is a prescribed health care profession for the purposes of the definition of 'practitioner' in section 1 of the <i>Pharmacists, Pharmacy Operations and Drug Scheduling Act</i>¹⁷ only for the purposes of prescribing the following drugs for use for emergency contraception: (a) [e]thinyl estradiol; (b) [l]evonorgestrel; (c) [n]orgestrel; (d) [p]rogestin."</p> <p>The Lieutenant Governor, with the advice and consent of the Executive Council of the BC legislature, and on the request of the Council of the College of Pharmacists of British Columbia, amended the <i>Drug Schedules Regulation</i>²² with the addition of a new schedule, Schedule IV (Prescription by Pharmacist): "Drugs which may be prescribed by a pharmacist in accordance with guidelines approved by the Council of the College of Pharmacists of British Columbia."</p> <p>The Schedule IV guidelines, as below, were adopted at the Council meeting of the College of Pharmacists of British Columbia in September 1999: "1. The pharmacist must demonstrate completion of an approved training program prior to prescribing emergency contraceptive medication. 2. Appropriate documentation must be maintained."</p>

closed.¹⁹ This enhanced availability enabled 57% of women to access ECs within 24 hours of unprotected intercourse and 87% to access ECs within 48 hours. On the basis of the known efficacy of these drugs, it can be concluded that pharmacist-initiated prescribing of ECs prevented a substantial number of unwanted pregnancies during the first two years of the program.

Regulatory implications

At the time of writing (spring 2004), Health Canada was considering a submission (from the Canadian Pharmacists Association, the Society of Obstetricians and Gynaecologists of Canada, and Paladin, the Canadian distributor of Plan B) to change the status of the levonorgestrel-only agent from prescription only (Schedule F) to non-prescription (see box p. 28).²⁶ The National Drug Scheduling Advisory Committee has recommended that this drug be listed as a Schedule II non-prescription product. Health Canada's ruling on this application is anticipated in fall 2004, so it is timely to examine the issues that practising pharmacists, pharmacy regulatory bodies, and provincial drug plans and private insurers will need to consider if Plan B becomes a non-prescription drug.

Scheduling options

Each provincial or territorial regulatory body determines how the decisions of Health Canada and the recommendations of the National Drug Scheduling Advisory Committee will be implemented. Manitoba, Ontario, New Brunswick, and Nova Scotia routinely use a "scheduling by reference" model, whereby recommendations from the National Drug Scheduling Advisory Committee are put into

effect immediately. However, each of the remaining provinces will need to specifically consider the federal decision and recommendation regarding Plan B. Their regulatory bodies will then need to decide on the appropriate provincial drug schedule. Scheduling options include adopting the National Drug Scheduling Advisory Committee recommendations, leaving Plan B as a Schedule I prescription drug, adding (or retaining) Schedule IV status (which permits independent prescriptive authority for both the combination estrogen-progestin ECs and the levonorgestrel-only EC), or changing the status of Plan B to Schedule II and reconsidering the schedule for the combination estrogen-progestin product if it is not already Schedule IV.

Whatever schedule a provincial regulatory body decides on for Plan B will then need to be evaluated to determine whether it creates a conflict with the status of the combination estrogen-progestin EC.

Different training protocols

Specially trained pharmacists in British Columbia, Quebec, and Saskatchewan can now prescribe both combination estrogen-progestin ECs and the levonorgestrel-only EC products directly to women. Should Plan B be transferred to non-prescription status, all pharmacists in those provinces will be able to provide the levonorgestrel-only agent from behind the counter, but only pharmacists with additional EC training will be able to offer the option of the combination estrogen-progestin product. In the other Canadian jurisdictions, which do not currently have independent prescriptive authority, pharmacists will be able to

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provide Plan B as a behind-the-counter drug but will not be able to offer the combination EC (however, the latter will continue to be available by physician prescription).

Another issue to consider is that if levonorgestrel were to become a Schedule II drug, special EC training for pharmacists would be optional. A standard protocol would not be required for the interaction between pharmacists and EC users, which might reduce the consistency of counselling and referral for regular birth control, treatment of STIs, and other community health care resources.

Reimbursement

The provincial drug plans in Quebec and Saskatchewan currently pay pharmacists for the counselling component of all pharmacist-initiated EC prescriptions, at \$15.00 and \$15.94, respectively. In British Columbia, pharmacies that have signed a contract with BC PharmaCare are paid a \$15.00 counselling fee for all pharmacist-initiated ECs. Pharmacies that have not signed the contract set their own counselling fee, usually \$25.00, paid by the woman requesting the EC.

In all three jurisdictions, drug cost and dispensing fees for EC prescriptions are paid by the patient or her drug plan, depending on individual patient coverage. Should Plan B become a non-prescription drug, then drug coverage issues for both this drug and the combination estrogen-progestin product must be carefully considered by government and private drug insurance plans. If Plan B is no longer covered, then accessibility to an EC for adolescents and low-income women could be limited to the combination estrogen-progestin product, through physicians' offices or through EC-certified pharmacists in the three provinces.

Ironically, this action could increase the barriers to access that the transfer to non-prescription status was designed to address. In the United Kingdom, where a pharmacy-only behind-the-counter levonorgestrel EC product was released in January 2001, the product was

priced at C\$45.00.²⁷ Sales figures for the levonorgestrel product, Levonelle, suggested that the majority of women who obtained the over-the-counter EC were working and were 25 to 35 years of age.²⁸ In response to these data and in an effort to reduce teenage pregnancies, many public health programs in the United Kingdom introduced programs to make ECs available free through community pharmacies for women up to 19 years of age.

Conclusions

We have described the history and mechanism underlying the health policy change in British Columbia that granted pharmacists independent prescriptive authority for ECs.

The initial evidence suggests that specially trained community pharmacists have improved access to ECs among women in all regions of the province. Traditional barriers to timely EC access have been reduced with this increase in qualified prescribers; the expansion of availability to convenient urban, rural, and remote locations; and the extended hours of pharmacy operation. As primary health care practitioners, pharmacists have demonstrated a willingness to provide counselling and referral for regular contraceptive methods, STIs, and follow-up care. By making ECs more readily available to women, pharmacists have actively contributed to a reduction in unwanted pregnancies and subsequent abortions.

Further reduction in barriers to access through behind-the-counter availability of Plan B is promising, if reimbursement issues are carefully considered and proactively addressed.

Finally, it will be important to gather and evaluate data to see whether emergency contraceptives provided by pharmacists fulfill their potential to reduce abortion rates in the province. ■

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