Ethical Issues for Pharmacists: Emergency Contraception

By

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For over 40 years, emergency contraception (EC) has been prescribed for women to reduce the risk of pregnancy after unprotected intercourse, including cases of unanticipated sexual activity, contraceptive failure, or sexual assault (1). Although the use of EC has expanded dramatically over the past two decades, unintended pregnancy due to contraceptive failure or unprotected intercourse remains a problem. The Canadian Pharmacists Association reports that approximately 50% of all pregnancies are unintended, resulting in an abortion rate of about 25% of all pregnancies (2). Shockingly, this high frequency of events has occurred despite the wide availability of contraceptive methods. According to 2001 Statistics Canada figures, emergency contraception has the potential to prevent 106,418 abortions (including 19,936 among teenagers) annually (3). Estimations in the United States predict that approximately 1.7 million unintended pregnancies and 800,000 abortions could be prevented each year by the widespread use of EC (4). Likewise, a United Kingdom study estimates that increased access to and awareness of EC could result in a halving of the abortion rate (2).

One of the important barriers to the use of EC has been lack of timely access to a physician. EC is only effective up to 72 hours after intercourse and its effectiveness decreases as time passes. Making EC available in pharmacies without a prescription has been promoted as a means of improving access and awareness. It is available without a prescription, and in some cases without a pharmacist’s intervention, in 39 countries, including France, the UK, Denmark and Norway (5). Experiences in other countries indicate that easier access does not lead to excessive use.

Currently in the United States, eight states (Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Washington) allow women to purchase EC directly from a pharmacy without a physician’s prescription. Pharmacists have collaborative practice agreements with the boards of pharmacy and physicians particular to each state and must complete specific training requirements in order to dispense EC. Some state requirements are stricter than others but in general they share the common characteristics of additional training requirements, monitoring of patient histories, attending continuing education on EC, and providing patients with a written fact sheet on EC (1).
On April 19, 2005, Health Canada changed the prescription status of the EC, Plan B, to make it a Schedule II (pharmacist only) product. This has put Canadian pharmacists in an interesting position. Most see this as an opportunity to practice pharmaceutical care, and advance the profession whereas others feel that it is against their moral beliefs to dispense this type of medication.

Days before Health Canada’s announcement, the US Food and Drug Administration (FDA) ignored the recommendations of its scientific advisers and refused to make emergency contraception available without a prescription by issuing a “non-approvable letter”. The fight to get Plan B and other EC over-the-counter or pharmacist only status, has long been an arduous process in both Canada and the United States. While these issues are being resolved pharmacists have to weigh their own ethical considerations on the matter, including when if ever, they will refuse to dispense EC, and what is the ethical motivation behind the refusal.

The debate over the use of EC has been extensive. Many applaud its use as an effective means to prevent unwanted pregnancies and subsequent abortions, whereas others view the “morning after pill” as a more convenient form of abortion. The Catholic Organization for Life and Family and other anti-abortion groups believe pregnancy begins with conception, not implantation. In a letter to Health Canada, the organization called levonorgestrel, the synthetic progestin component of Plan B, an “abortifacient” (3). Scientifically this is incorrect. EC prevents a woman from becoming pregnant by stopping ovulation, fertilization, and implantation. The so-called “abortion pills” (Mifeprax (mifepristone) also called RU-486) work after a woman becomes pregnant. These pills cause the uterus to expel the egg, ending the pregnancy. EC has no effect on the fetus once a woman is already pregnant (6).

In July of 1999 the FDA approved Plan B, the first progestin only EC available in the United States, and currently the only marketed product in the U.S. for this indication. Plan B contains levonorgestrel 0.75 mg and is taken as two tablets 12 hours apart. This regimen, like all other EC, is most effective when taken within 72 hours of intercourse. It can, when used correctly, reduce the risk of pregnancy by 89% after a single act of unprotected sex. Effectiveness declines as the time between intercourse and the start of treatment increases. The levonorgestrel regimen also has a lower incidence of adverse effects compared to other EC regimens that contain estrogen (1).

In an effort to improve patient access to EC, an application to switch Plan B to over-the-counter status was filed with the FDA. The process began in February 2001 when the Center for Reproductive Rights filed a petition with the FDA on behalf of about 70 medical, public health, and other organizations to grant over-the-counter status to Plan B. However, no decision was issued for the petition (5).
The manufacturer of Plan B, Barr Pharmaceuticals, Inc. then filed a second petition in 2003. FDA advisory panels, including the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health, found that Plan B meets the criteria for availability without a prescription, and recommended granting over-the-counter status by a vote of 23-4. Five months later, despite these recommendations, the FDA chose to deny the petition, citing concerns about adolescent use and increases in promiscuity (5).

A dozen members of Congress called for the resignation of key FDA officials for denying the over-the-counter petition based on political and ideological, not scientific reasons. Forty-one members of Congress asked that the FDA reconsider its decision (5).

In 2005, new studies rebutted the FDA's claim of increased promiscuity, finding that while advanced access to EC does increase the chances of using EC, increased access does not alter sexual behavior or the risk for contracting STIs (7-10). These studies also revealed that the use of EC does not result in a failure to start or continue use of regular contraceptive methods; the majority of women in their 20s had used regular contraception before the use of EC; Providing EC to adolescents is not associated with more unprotected sex.

By January 21, 2005 the FDA was supposed to issue its ruling on Barr Pharmaceuticals, Inc.'s subsequent application, requesting over-the-counter status of EC for women who are 16 and older. The FDA did not meet this deadline. 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 the over-the-counter age restrictions, the FDA has opened a 60-day public comment period to address EC over-the-counter implementation strategies (5).

The FDA has posted its reasoning for denying Plan B over-the-counter status on its website. It states that some members of the original advisory committee, including the Chair, raised questions concerning whether the actual use data were extractable to the overall population of nonprescription users, mainly because of insufficient data in younger age groups. This is why they requested additional information from the sponsor pertaining to adolescent use. The FDA, on completing its review of the requested supplemental application, concluded that the application could not be approved at this time because 1) adequate data was not provided to support a conclusion that young adolescent women can safely use Plan B for emergency contraception without the professional supervision of a licensed practitioner and 2) a proposal from the sponsor to change the requested indication to allow for marketing of Plan B as a prescription-only product for women under 16 years of age and a nonprescription product for women 16 years and older was incomplete and inadequate for a full review. Therefore, FDA concluded that the application was not approvable (11).
Without over-the-counter status, practitioners and advocacy groups have tried to make EC available through other means. Currently, in eight US states, patients can obtain EC without a physician’s prescription: Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Washington. In these states, pharmacists are allowed to provide EC through collaborative practice agreements with the board of pharmacy and physicians particular to each state. Pharmacists must complete specific training requirements in order to dispense EC. Some state requirements are stricter than others but in general they all require additional training requirements, monitoring of patient histories, attending continuing education on EC, and providing patients with a written fact sheet on EC. Overall, the key requirement for pharmacists in each of these states is to be able to counsel patients on the proper use, side effects, risks and benefits associated with EC (1).

One particular model of practice, the Collaborative Agreement EC Pilot Project was launched in Washington State in July 1997 by a coalition of health care providers and advocacy organizations, led by PATH (Program for Appropriate Technology in Health). This innovative project enabled thousands of women in Washington to receive EC and instruction for the correct use of the medication, directly from their pharmacists. More than 800 pharmacists and pharmacy students received training for prescribing and counseling about EC, which enabled them to enter collaborative drug-therapy agreements with prescribing clinicians, and gave them the authority to dispense EC directly to women (5). In the first 13 months of the project, 9,333 EC prescriptions were provided, preventing between 504 and 2,100 pregnancies, about half of which would have ended in abortion (12).

In September 2005, Massachusetts became the eighth state to establish an EC Collaborative Practice agreement. The state House and Senate overrode Governor Romney’s veto of July the same year, resoundingly endorsing a Massachusetts bill that will not only allow for EC to be dispensed by a pharmacist without a prescription, but will also require that EC be made available in hospital emergency rooms for sexual assault survivors. This bill should take effect by mid to late December 2005 (13-14).

Other interesting practices include that in California. Their program allows women to be provided EC before it is needed, so it is on hand in case of an emergency (15).

Other states have either had proposed bills die or have bills in progress, that propose the dispensing of EC by pharmacists in accordance with a protocol with a physician, physician assistant, or nurse practitioner. Kentucky, Illinois, Maryland, and Texas have recently had bills rejected, whereas New Jersey, New York, Oregon, and Vermont all have bills currently in progress (16).
In Michigan, there is currently no known activity promoting direct pharmacy access to EC. The University Of Michigan College Of Pharmacy and the Michigan Pharmacists Association have plans to discuss this issue. In 2002, Planned Parenthood Advocates of Michigan surveyed pharmacists to determine whether they stocked EC. One of the key findings was that pharmacies were not seeing any demand for EC and, as a result, medications were expiring. Clearly, Michigan could benefit from increased education on EC. Perhaps in anticipation of future lobbying for over-the-counter status, the HB 5311 bill was introduced to the state house in October 2005 to propose that EC be dispensed only as a prescription drug. The outcomes of this bill will have to be closely monitored (17).

Internationally, EC is available without a prescription, and in some cases without a pharmacist’s intervention, in 39 countries, including Albania, Belgium, Canada, Denmark, Finland, India, Israel, Morocco, Norway, Portugal, South Africa, Sweden, and the United Kingdom. (5).

Of particular interest are France’s policies. 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. 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. 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. In October 2000, the French Parliament amended the law to once again allow school nurses to dispense EC (5).

Canada also has a progressive approach to EC. On December 1, 2000, specially trained pharmacists in British Columbia became the first in Canada to be formally granted independent prescriptive authority for EC. The provincial government implemented this health policy initiative to reduce barriers to access for this time-sensitive birth control option, as over 14,000 pregnancies were terminated with an abortion in British Columbia in 1998, 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 (18). Pharmacists underwent a similar training program to that used in Washington State and were required to document their interaction with patients. A form was designed to obtain the patient’s informed consent for the EC interview protocol, and to capture data including: 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, and the type of referrals to health care professionals (e.g., for sexually transmitted infections or regular birth control) (18).

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 (18).

A 2005 study sought to determine changes in EC use after the British Columbia policy was introduced and to analyze EC use with data generated by the policy. The number of EC prescriptions increased from a pre-policy mean of 8805 in the years 1996 to 2000 to a post-policy total in 2002 of 17 794. Physicians prescribed Plan B less frequently than did pharmacists. The frequency of EC use was highest among women aged 20–24 years across all study years, and all age groups demonstrated a post-policy increase in use. On average, 2.1% of the women received an EC three or more times a year over the period of the study. Analysis of pharmacist treatment consent forms used in 2001 and 2002 showed that 56.2% of women receiving an EC reported using a method of birth control that had failed, 55.7% of pharmacist-provided ECs were obtained within 24 hours after unprotected intercourse, 1.1% of ECs were obtained for future use and women tended to seek ECs when unprotected intercourse occurred at the time of highest risk of pregnancy in their menstrual cycle (19).

Quebec and Saskatchewan adopted the British Columbia independent prescriptive authority model for EC 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 (18, 20).

On April 19, 2005, Health Canada changed the prescription status of the EC, Plan B, to make it a Schedule II product. This means that Plan B will be available behind-the-counter, held in an area of the pharmacy without public access or opportunity for self-selection by patients, and will require professional intervention from the pharmacist at the point of sale (21).

The move to nonprescription status came after extensive lobbying by the Society of Obstetricians and Gynecologists of Canada (SOGC), the Canadian Pharmacists Association (CPhA), the Women’s Health Network, the Royal College of Physicians and Surgeons of Canada, the Canadian Medical Association, Planned Parenthood Federation of Canada, the Federation of Medical Women of Canada, and the Canadian Nurses Association and others (21). Most importantly, levonorgestrel satisfies all of the criteria for
nonprescription status, including a long history of safe and effective use, low incidence of side effects (most frequent being mild nausea) and a simple and easily explained manner of use (2).

According to a survey conducted in 2004, this is a decision that is supported by 70% of Canadians and 81% of Quebecers. Nationally, 80% of 18-24 year olds approved of Plan B being made available without a prescription (21).

In Canada, 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 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, or adding (or retaining) Schedule IV status (which permits independent prescriptive authority, like in British Columbia, Saskatchewan, and Quebec) (18).

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 counseling and referral for regular birth control, treatment of STIs, and other community health care resources (18).

While many organizations are pleased to finally see increased availability of EC, they also foresee some potential problems. Foremost is the fact that pharmacists can refuse to dispense the drug, which could impede access in areas with only one drug store. Some pharmacists will undoubtedly refuse. Pharmacists for Life Canada, a pro-life lobby group, views EC as synonymous to abortion (2).

In order to deal with this situation, the individual provincial colleges of pharmacy have position statements on the refusal to fill for moral or religious reasons (22-23). The Ontario College of Pharmacy states that if a pharmacist has ethical concerns about providing emergency contraception, they will need to declare the concern and arrange (with their peers) where they will direct patients seeking this medication and service (24). This is pursuant to the College’s Position Statement on Refusal to Fill for Moral or Religious Reasons drafted in 2001. The paper states:
Pharmacists shall hold the health and safety of the public to be their first consideration in the practice of their profession. Pharmacists who object, as a matter of conscience, to providing a particular pharmacy product or service must be prepared to explain the basis of their objections. Objecting pharmacists have a responsibility to participate in a system designed to respect a patient's right to receive pharmacy products and services. The following clauses, reflect the need to meet a patient's requirements for pharmacy products and services while respecting a pharmacist's right of conscience:

1. A pharmacist is permitted to decline providing certain pharmacy products or services if it appears to conflict with the pharmacist's view of morality or religious beliefs and if the pharmacist believes that his or her conscience will be harmed by providing the product or service. Objections should be conveyed to the pharmacy manager not the patient.

2. The individual pharmacist must insure an alternate source, to enable the patient to obtain the service or product that they need. Any alternate means must minimize inconvenience or suffering to the patient or patient's agent (22).

The Saskatchewan Pharmacists Association has a similar document entitled “Statement Regarding Pharmacists’ Refusal to Provide Products or Services for Moral or Religious Reasons.” It states that “objecting pharmacists cannot abandon their ethical duty of care to the patient, and respect of the patient's right of autonomy to make informed decisions to receive pharmacy products and services based on objective and accurate information.” It goes on to state “it would be improper and unethical conduct if the pharmacist used the opportunity to promote his/her moral or religious convictions, or engage in any actions, which demean the patient.” It is in the pharmacist’s duty of care to “refer the patient to, or pre-arrange access to an alternate source, to enable the patient to obtain the service or product that they need.” In other words, a pharmacist may refuse to dispense EC on moral grounds as long as they provide the patient with alternative access (23, 25).

Comparably, in the US the states also have refusal statutes. In 34 states, refusal statutes refer only to abortion. In 13 states they pertain to both abortion
and contraception. Eight of these 13 states explicitly allow individuals to refuse to provide services related to birth control, contraception, and/or family planning. Four of these states explicitly permit pharmacists to refuse to dispense contraceptives, whereas the additional four states have broad refusal clauses that do not specifically include pharmacists, but may apply to them (26).

According to American Pharmacists Association (APhA), refusal clauses that allow an expression of religious beliefs can be considered acceptable if pharmacists provide an adequate plan for referral (27-28). The APhA’s own “Pharmacist Conscience Clause” states “APhA recognizes the individual pharmacist’s right to exercise conscientious refusal and supports the establishment of systems to ensure patient’s access to legally prescribed therapy without compromising the pharmacist’s right of conscientious refusal” (27). Health care must not be disrupted or obstructed by either untold delay or barrier. Professionals who object to providing a service need to do so consistently and provide forewarning to their employers and clientele, but “should the alternate means provided by the employer fail to operate … in a timely fashion … then the pharmacist has a duty to the patient to dispense the medication” (28).

Pharmacists exercising their right to refuse to fill prescriptions have recently made headlines. In Illinois, state health authorities were informed that two women were unable to have prescriptions filled for EC at a chain pharmacy in Chicago. This prompted the Governor to issue an emergency order requiring “pharmacies” to dispense contraceptives. Under this order, pharmacies that sell contraceptives are required to fill valid, legal prescriptions for these medications without delay. As written, the rule did not appear to permit pharmacists to protect patients from medications contraindicated because of allergy or drug-related interactions. Nor did the rule permit pharmacists to transfer prescriptions if they had any objections to filling the prescriptions (29).

This sparked much debate and on communication with APhA, the Illinois Pharmacists Association (IPhA) and the American Society of Health-System Pharmacists (ASHP), the Governor clarified that the order is not intended to conflict with pharmacists’ professional judgment. The order is in effect for 150 days, and the state has filed charges of improper care and dispensing against the pharmacy involved in the case (29).

In response to the Prevention Magazine article entitled “Access Denied: Find out why growing numbers of doctors and pharmacists across the U.S. are refusing to prescribe or dispense birth control pills” the American Pharmacists Association (APhA) stated that while supporting patients’ right to access their legally prescribed medications, the APhA also supports the pharmacist’s right of conscience, which comes with responsibility to assure patient access to prescribed medications. The APhA suggests that another pharmacist on duty may complete the prescription or patients are proactively directed to pharmacies where certain therapy is available (30).
Pharmacists who refuse to dispense birth control cite their religious, moral, ideological, and personal objections to the use of contraceptives (28). A 2003 study about the attitudes and knowledge base of Pennsylvania pharmacists found that 65 percent had negative feelings regarding EC, and that 13 percent believed that EC are abortifacient (31).

A survey conducted at Wayne State University’s Eugene Applebaum College of Pharmacy in Detroit Michigan, was analyzed to determine future pharmacist’s opinion on the refusal to dispense EC and whether or not the pharmacist should dispense Plan B as an over-the-counter drug. The results are summarized in Tables 1-2.

Table 1: Main survey questions

<table>
<thead>
<tr>
<th>Is there any situation in which you would not dispense emergency contraception?</th>
<th>Should Plan B be dispensed by the pharmacist as an over-the-counter drug?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>25%</td>
<td>75%</td>
</tr>
</tbody>
</table>

Table 2: Situations in which EC would not be dispensed

<table>
<thead>
<tr>
<th>Due to Personal Beliefs</th>
<th>Patient’s Age (Too young)</th>
<th>Patient wanted some on hand “just in case”</th>
<th>Patient has had this medication more than once before</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>20%</td>
<td>40%</td>
<td>35%</td>
</tr>
</tbody>
</table>

The majority (75%) of students surveyed were women and the mean age was 25 years old. There was no correlation between age and response, but interestingly men answered at the same frequency for the first question (75%), but only 50% thought that Plan B should be dispensed by a pharmacist as an over-the-counter drug, a figure lower than the overall average of 65%. For those students that answered there are certain situations in which they would not dispense EC, the scenarios they cited most frequently were the patient wanted some on hand “just in case”, followed by the patient has had this medication
more than once before, then the patient’s age. Some said they would not dispense the medication to patients less than 16 whereas others said less than 18. The religious background of the students surveyed is summarized in Table 3.

Table 3: Religious affiliation as stated by individuals

<table>
<thead>
<tr>
<th>Christian</th>
<th>Catholic</th>
<th>Lutheran</th>
<th>Protestant</th>
<th>Hindu</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>57%</td>
<td>9%</td>
<td>3%</td>
<td>3%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Most students surveyed were Catholic. When considering the Catholic Church’s stance on birth control and contraception it was a surprise that in sub-group analysis 72% of students who designated themselves as Catholics answered no to the first question and 67% answered yes to the second question, numbers quite similar to the whole population. Religion did not have as strong an influence as expected.

The results of this survey infer that the majority of pharmacy students would dispense EC and would like to see Plan B become an over-the-counter drug that would be dispensed by the pharmacist.

Clearly, EC remains a controversial topic. Currently eight states permit pharmacist dispensing of EC without a physician’s prescription, and four other states have legislation in progress that would grant the same status. Health Canada has changed the scheduling of Plan B to behind-the-counter, meaning that it can now be purchased after conversation with a pharmacist.

The benefits of making EC more accessible include fewer unwanted pregnancies and abortions. This would be particularly significant, as the rate of unintended pregnancy in Canada and the United States is 50%, and the abortion rate in Canada is 25% of all pregnancies. But as the dispensing of EC becomes more frequent some pharmacists are finding themselves in a moral dilemma, their beliefs and their duty to honor the autonomy of their patients are in conflict. Boards of pharmacy and professional associations have stood by pharmacists’ right of conscience, but have stated that pharmacists who refuse to fill prescriptions for moral and religious reasons must make alternative arrangements for patients. This seems like a happy medium but some pharmacists still feel they should not be obligated to participate in the process at all. The issue is perplexing and obviously still needs to be sorted out. In the meantime it is important for pharmacists to examine their own beliefs regarding EC and decide what they are willing and not willing to do in the course of their practice. They must then place themselves in professional situations that allow them to practice without the threat of moral conflict, so they can fulfill their obligations to their patients.
References


