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The Developing Role of Pharmacists in Patient Access to Emergency Contraception

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Abstract

Unintended pregnancy and subsequent abortion remain major public health issues in many countries, despite evidence that post-coital emergency contraceptives have a good safety profile, are easy to use, and are effective in preventing unwanted pregnancies. Although emergency contraceptives have been prescribed in developed countries for more than 25 years, abortion rates have continued to rise steadily in many jurisdictions. Barriers to the use of emergency contraceptives reduce ready access of women to this birth control option. Because the effectiveness of emergency contraceptives is time dependent, establishing prescribing and dispensing mechanisms that are convenient to women is crucial to their ability to use the therapy in a timely manner.

Emergency contraceptives in developed countries are traditionally prescribed by physicians in organized healthcare settings. In these countries, pharmacists are ideally situated to improve patient access to emergency contraceptives, since community pharmacies are widely available in both urban and rural settings and are open extended hours. Innovative initiatives using a variety of regulatory mechanisms now allow pharmacists a greater role in prescribing and distributing emergency contraceptives. In Washington State, USA, pharmacists entering into a collaborative drug therapy agreement with a physician or nurse practitioner can initiate emergency contraceptives based on a prescribing protocol. Several local programs in the United Kingdom have utilized accredited community pharmacists to supply emergency contraceptives using a patient group directive. In British Columbia, Canada, specially-certified pharmacists with independent prescriptive authority utilize an informed consent during the interactive consultation with the potential emergency contraceptive user. In yet other jurisdictions, emergency contraceptives have been transferred to over-the-counter (OTC) status.

Relevant public health research questions can now be posed. Future studies will be able to compare the effectiveness of various regulatory mechanisms to expand access, to identify and address potential drawbacks of pharmacist-initiated[1] emergency contraceptives, and to explore whether pharmacist-initiated prescriptions represent expanded access or simply a transfer of the prescribing of these agents from physicians to pharmacists. Countries with OTC emergency contraceptives will be able to explore the relationship between varying levels of pharmacist interaction with emergency contraceptive users and health outcomes, and to investigate whether the change in prescriptive status has resulted in unintentional barriers to access for populations such as teenagers and those with restricted discretionary income. These findings will provide valuable new information on the impact of initiatives designed to expand access to emergency contraceptives.

1 'Pharmacist-initiated' refers to emergency contraceptive prescriptions that are provided to patients by pharmacists, without the woman first needing to visit a physician.

1. Public Health Issues of Unintended Pregnancy and Subsequent Abortion

Emergency contraception has a good safety profile, is easy to use, and is effective in reducing the incidence of unwanted pregnancies after unprotected sexual intercourse or contraceptive failure.[1-3] For more than 27 years, emergency contraceptives have been prescribed in developed countries by family physicians and gynecologists, and in family planning clinics and emergency departments.[4] Nevertheless, despite increased international awareness and knowledge of this contraceptive option, abortion rates continued to rise steadily between 1974 and the mid-1990s and have remained high since then.[5-7] Worldwide, an estimated 50 million pregnancies are terminated each year.[8]

Barriers to emergency contraception may be very different in the developed world than in developing countries, where reproductive health products such as emergency contraceptives are often available over-the-counter (OTC).[9,10] In the present review, we focus on an enhanced role for community pharmacists to expand access to emergency contraceptives in three developed countries: the US, the United Kingdom, and Canada. Table I summarizes pregnancy and abortion rates in all age groups in these three countries, and in two specific jurisdictions, Washington, USA and British Columbia, Canada. As an example of the magnitude of this issue, more than 14 600 pregnancies were terminated with an abortion in British Columbia in 1999.[11] As noted in table I, this represents almost 24% of all pregnancies, more than 56% of pregnancies in women aged 15 to 19 years and 36% in women aged 20 to 24 years. Regional disparities in access to abortions and emergency contraceptives in remote and rural districts of the province[11] call attention to the difficulties in providing women with ready access to reproductive choices.

This review specifically focuses on three innovative international programs in developed countries that have utilized expanded roles for community pharmacists to improve patient access to emergency contraceptives.

1.1 Therapeutic Options for Emergency Contraception

High-dose oral hormonal agents are the most widely used method of emergency contraception. Other methods such as the post-coital insertion of a copper-bearing intrauterine device are also available, although not widely used.[17] While the precise mode of action of emergency contraceptives in preventing pregnancy is currently not known, the agents likely act at several critical stages of the reproductive cycle by inhibiting or delaying ovulation, and possibly by interfering with fertilization or inhibiting endometrial implantation.[17,18] Two regimens are commonly used for emergency contraceptive use. The first is the Yuzpe regimen,[4] which consists of two doses of a combination estrogen/progestogen (progestin) product (100μg of ethinylestradiol and 0.5mg of levonorgestrel), with the first dose administered within 72 hours of intercourse and the second dose 12 hours later. Recent research by Rodrigues et al.[19] suggests that the interval for which the Yuzpe regimen is effective in reducing the risk of pregnancy can be extended to 120 hours. The second type of emergency contraceptive agent is a progestogen-only product containing levonorgestrel 0.75mg, with the first dose within 72 hours of intercourse, and the second dose 12 hours later. The most frequently quoted overall estimates of efficacy are about 75% for the Yuzpe combination agents[3] and 85% for levonorgestrel,[20] although Ho and Kwan[21] has reported a efficacy of levonorgestrel closer to that of the Yuzpe regimen. Both regimens are most effective when initiated within 24 hours of unprotected intercourse, with efficacy decreasing over time.[22] Table II describes the availability and costs of emergency contraceptive agents in the United Kingdom, the US, and Canada.

The safety of emergency contraceptives has been well reviewed[23-25] and the agents are considered to be 'extremely safe, particularly when compared to the risks of pregnancy'.[24] Levonorgestrel is better tolerated than combination estrogen/progestogen agents, with an absolute reduction of 27% in the incidence of nausea (50.5 *vs* 23.1%) and 13.2% in the incidence of vomiting (18.8 *vs* 5.6%), in addition to significantly less dizziness and fatigue.[20] Contraindications that usually apply to oral contraceptives are less of a concern with emergency contraceptives since they are used only within a 24-hour period of time.[26]

Table I. Pregnancy and abortion rates per 1000 women aged 15 to 44 years in Washington State, the US overall, the UK, British Columbia, and Canada overall

Rate/1000 women aged 15-44 years	Washington, USA	USA	UK	British Columbia, Canada	Canada
Pregnancy rate	85.1[12]a	104.7[13]b	74.0[14]c	68.2[11]a	67.3[15]c
Abortion rate	20.9[16]a	20.0[6]d	16.8[7]c	16.2[11]a	15.6[5]

a 1999.
b 1996.
c 1997.
d 1997.

Table II. Availability and approximate out-of-pocket costs ($US, 2002 values) of emergency contraceptives in the US, the UK and Canada

Emergency contraceptive regimen	US	UK	Canada
Combination estrogen/progestogen (progestin)	Ovral®[a]	N/A	Ovral®[a]
(Yuzpe regimen)			
Physician-prescribed	$5-45[b]	N/A	$5[c]
Pharmacist-initiated	$35-$45[d]	N/A	$2[e]
Behind-the-counter	N/A	N/A	N/A
Levonorgestrel regimen	**Plan B®**	**Levonelle-2®**	**Plan B®**
Physician-prescribed	$5-45[b]	No charge[f]	$15[c]
Pharmacist-initiated	$35-$45[d]	No charge[g]	$31[e]
Behind-the-counter (pharmacy only)	N/A	$29	N/A

a Use of tradenames is for identification purposes only and does not imply endorsement.
b Varies dependent upon whether insurance is billed (insurance co-pays are frequently under $10).
c Includes drug cost plus dispensing fee.
d Drug cost plus counselling fee plus antiemetic.
e Includes drug cost plus dispensing fee plus counselling fee.
f National Health System doctors.
g Pharmacists and nurses involved with patient group directives.
N/A = product not available.

1.2 Barriers to Timely Access

A number of barriers have been identified that interfere with ready access to emergency contraceptives and proper use of the products.[27] Barriers include lack of knowledge among the general public and healthcare professionals,[1,28,29] lack of timely access to a physician, family planning clinic or emergency department within the crucial 72-hour time frame, family planning clinic or emergency department,[29] unwillingness of young women to request medication from their physicians,[30] reluctance of healthcare service providers to provide this method of birth control,[1] and, until recently, a scarcity of products marketed specifically for emergency contraceptive use.[1] The term 'morning-after' pill is also a barrier because of the implication that the product can only be used the next day.[31] While many women are aware that emergency contraceptives are available,[32,33] they are often unsure where the agents may be obtained. In a study of abortion clients in New Zealand, more than half of the women stated that they would have used emergency contraception if it had been available over the counter or if they had received the method before needing it.[34] Since the effectiveness of emergency contraceptives is time dependent, establishing prescription and dispensing mechanisms that are convenient to women is critical to their ability to use the therapy in an appropriate manner.

1.3 Endorsement of Enhanced Access to Emergency Contraceptives

The 1995 consensus conference of international and World Health Organization (WHO) experts held in Bellagio, Italy concluded that there was a clear need for emergency contraception, and that 'women everywhere should have access to these safe and effective ways to prevent unwanted pregnancy'.[1] The British Royal College of Obstetricians' and Gynaecologists' Guidelines in 1995 reinforced the view that hormonal emergency contraception has a very good safety profile and that concern about repeated use of the emergency contraceptive medication was not justified.[35] Following concerted lobbying by family planning and women's organizations, in 1997 the US Food and Drug Administration (FDA) stated that six brands of oral contraceptives were safe and effective for use as emergency contraceptives and published the appropriate dosages.[36] In Canada, the Society of Obstetricians and Gynecologists of Canada endorsed expanding access to emergency post-coital contraception in 1998. From a public health perspective, the Canadian motion stated that hormonal emergency contraceptives should be made available through a pharmacist without prescription, after counselling regarding ongoing sexual healthcare.[2,37]

1.4 Innovative International Programs to Enhance Access

A number of international initiatives have been designed that allow healthcare providers other than physicians to prescribe and dispense emergency contraceptives. In some settings in the US, nurse midwives, nurse practitioners and physician assistants have independent authority to prescribe emergency contraceptives, or may be able to prescribe the drugs under protocols established by a physician.[27] In the United Kingdom, trained family planning nurses have been able to offer emergency contraception services, with authorization from a physician, either in person or by telephone.[38,39] Community pharmacists in a number of jurisdictions in Canada, the US and the United Kingdom are now able to initiate prescriptions for emergency contraceptives, and three distinct programs with individualized regulatory mechanisms are described in section 2. To further reduce perceived barriers to the prompt, effective use of this preventative therapy,[40,41] deregulation of hormonal emergency contraceptives from prescription-only status to pharmacy status has now been adopted in Albania, Belgium, Denmark, France, Norway, Portugal, South Africa, Sweden and the United Kingdom.[42,43] This regulatory change

allows OTC sale or supply of emergency contraceptives by a pharmacist.

2. Models of Pharmacist-Initiated Emergency Contraceptives

Pharmacists are ideally situated and qualified to improve patient access to emergency contraception and to provide appropriate sexual health advice. Community pharmacies are widely available in urban and rural settings, have extended hours of operation, are relatively non-threatening locations to visit and there is ready access to a healthcare professional without an appointment. Unique regulatory mechanisms granting pharmacists the authority to initiate emergency contraceptive prescriptions were required, because in the traditional model of healthcare, only physicians have authority to prescribe these medications. While not inclusive of all pharmacy programs designed to improve access to these agents, the three mechanisms described below provide a range of prototypes for consideration. These unique solutions to improve the quality of women's healthcare have focused national and international attention on the outcomes of these expanded access initiatives.

2.1 Collaborative Drug Therapy Agreement: Washington, United States

Emergency contraceptives are available in Washington State by prescription from physicians practicing in private practice, in health maintenance organizations, in emergency departments, and in Planned Parenthood and community-based clinics. In 1997, Washington professional and advocacy groups began to explore innovative ways to further expand access to emergency contraceptives using a pharmacy regulatory mechanism that had been enacted in this state in 1979.[44] The legislation allowed pharmacists to have delegated prescriptive authority for specific drugs once a collaborative drug therapy agreement protocol had been developed with a licensed prescriber, and had been formally reviewed by the State Board of Pharmacy.[45] The protocol describes the types of drugs involved, the decision criteria used in the pharmacist's prescribing, the method of documenting decisions and includes a plan for periodic feedback and review of the pharmacist's prescribing activities with the authorizing licensed prescriber.[44]

Washington became the first jurisdiction in the US, in 1998, to expand access to emergency contraceptives through the use of specially-instructed pharmacists who entered into collaborative drug therapy agreements with physicians.[46] The agreements are filed with the Board of Pharmacy and are to be renewed at least every 2 years.[47] Under this mechanism, emergency contraceptives can be prescribed to women of any age, and the agents can be initiated for either immediate or future use. Most pharmacies charge around $US35 to $US38 for emergency contraceptive services, which includes the drug cost, an antiemetic and the pharmacist's time to assess, counsel and document the interaction with the patient (table II).[48]

In the 16-month pilot project, pharmacists dispensed 11 969 emergency contraceptives from 130 pharmacies directly to patients without the woman first seeing a physician.[47] Preliminary findings of a survey of women who received emergency contraceptives suggested that the majority of women had received emergency contraceptives within 24 hours of unprotected intercourse, during evenings, weekends, or holidays and for contraceptive failure. Almost 42% reported that if they had not received emergency contraceptives directly from a pharmacist, they would have taken no action and would have waited to see if they became pregnant.[48] A recent study modelling the cost and outcomes of pharmacist-prescribed emergency contraception suggests that obtaining emergency contraceptive pills directly from a pharmacist reduces the number of unintended pregnancies and is cost saving.[49]

Washington has a segmented public/private healthcare system. Consequently, there are no state-wide prescription or medical services databases that record emergency contraceptive-related data for all residents. It is difficult to assess the impact of the pilot program on overall utilization of emergency contraceptives, as baseline data on the patterns and prevalence of physician-initiated emergency contraceptives are not available. While population-based statistics on pregnancy and abortion rates are available from the Washington State Department of Health, any observed changes are likely multi-factorial and can not be solely explained by changes in emergency contraceptive usage. Nevertheless, the pilot project data do provide support for the notion that expanded access through pharmacist-initiated emergency contraceptives can increase the utilization of these post-coital agents. Using this pharmacist collaborative agreement model, a pilot study with 33 community pharmacies has recently been initiated in Toronto, Canada, and a state-wide program was initiated in California in January 2002.

2.2 Patient Group Directives and Over-The-Counter (OTC) Pharmacy Sales: United Kingdom

The continued high incidence of unplanned pregnancies and subsequent terminations in the United Kingdom, particularly among teenagers, has recently led to strategies and statutory changes utilizing community pharmacists to improve availability to emergency contraceptive products. Successful pilot projects

have been initiated in a number of regions, including Manchester, South London, South Derbyshire, Hull and East Yorkshire.[50-52] Health authority doctors and managers sign group protocols (patient group directives) that authorize designated accredited pharmacists in specific geographically-selected locations to supply emergency contraception. Once pharmacists have participated in compulsory training workshops, they are accredited for a period of two years, after which time the group protocol will be reviewed and the pharmacists re-accredited. Emergency contraceptives are available to clients of any age, are free of charge, and usually the woman takes the first dose while in the pharmacy. A private 15- to 20-minute consultation is conducted to determine suitability and provide information on long-term contraception, safe sex and community resources. Teenagers are issued with free condoms and contraceptive advice if they are not using regular contraception. The client consultation form completed during the interview is kept for 2 years. Pharmacists are reimbursed about $US15 for counselling plus $US7 for the cost of the medication by the National Health Service (table II).[52]

The legal reclassification of levonorgestrel 750μg from a prescription-only medicine to a pharmacy status product in January 2001 provided a second mechanism to improve availability.[42] Pharmacy-only OTC sales are available only to women aged 16 years and over, and the product costs approximately $US29 (table II). The emergency contraceptive product is available from any pharmacist who decides to stock the pharmacy-licensed product. The Royal Pharmaceutical Society of Great Britain has issued guidelines on the pharmacy supply of emergency hormonal contraception.[53] While it is not mandatory for the pharmacist to keep documentary evidence of supply, it is recommended as good pharmacy practice to do so. While the product may be taken away from the pharmacy for consumption at a convenient time, the provision of emergency contraceptives in advance of need is not currently recommended.[53] The long-term impact of these multidimensional programs to increase access to emergency contraceptives will be seen in trends over time in pregnancy and abortion rates. The General Practice Research Database gives person-based data that can be used to determine changes over time in physician-prescribed emergency contraceptives, but does not include community clinic or hospital prescriptions.

2.3 Independent Prescriptive Authority: British Columbia, Canada

Emergency contraceptives are traditionally available in British Columbia through various healthcare sources. Physicians can write a prescription for an emergency contraceptive, which is then filled in a community pharmacy and the patient pays the drug cost and a dispensing fee. Physicians may also choose to have emergency contraceptives available in their office, which they may provide at no or low cost to the patient without a prescription. Other no or low cost mechanisms for physician-provided emergency contraceptives include Planned Parenthood clinics, community health and youth clinics, student medical services and emergency departments. Nevertheless, the high level of abortion (16.2 per 1000 women aged 15 to 44 years)[11] in the province suggested to the British Columbia Ministry of Health that emergency contraceptives were underutilized in the province, either from barriers to timely access or lack of public awareness. Pharmacists were granted statutory authority by the provincial legislature to independently prescribe emergency contraceptives commencing December 1, 2000. The regulatory amendment conferred prescriptive authority on specially-instructed certified pharmacists to initiate a prescription for emergency contraceptives directly to women of any age, either for immediate use or for use in the future.[54] Participation in the program is voluntary, and once pharmacists receive 4 hours of standardized training they are eligible to become registered with the College of Pharmacists to prescribe. An 'informed consent for emergency contraception' is completed during the 10- to 15-minute confidential pharmacist-patient interview prior to provision of the emergency contraceptive agent; referrals are made for regular birth control, for assessment of sexually transmitted infections (STIs) and to other community services. The patient pays the drug cost, the dispensing fee ($US5) and a pharmacist counselling fee ($US16) for the emergency contraceptive agent (table II). As prescription, medical and hospital services for all British Columbia residents are recorded in interlinked HealthNet databases, the impact of pharmacist-initiated emergency contraceptives on patterns and trends in emergency contraceptive utilization over time can be monitored. Both patient-specific and population-based pregnancy and abortion outcomes can be determined. Enabling legislation has recently been passed in Quebec permitting the initiation of a province-wide program using the independent prescriptive authority model developed in British Columbia.

2.4 Proposed OTC Regulatory Changes in North America

A Canada-wide initiative of physician, pharmacist and women's advocacy organizations was established in May 2000 to implement strategies to make emergency contraception more available to women in Canada and to raise awareness of emergency contraception among the general public and healthcare providers.[55] In March 2002, a joint submission was made by the Soci-

ety of Obstetricians and Gynaecologists, the Canadian Pharmacists Association, and the Canadian distributor (Paladin Labs Inc. based in Montreal) of Plan B® to Health Canada. The proposal requested that the dedicated progestogen-only emergency contraceptive be transferred from prescription status to non-prescription pharmacy-only behind-the-counter status. Behind-the-counter, in contrast to OTC, means that the emergency contraceptives would be kept behind the pharmacists' counters instead of being available and unsupervised on the shelves over the counter. A related request for transfer to OTC status for the progestogen-only agent is also planned for submission to the US FDA in 2002.

3. Preliminary Estimated Impact of Pharmacist-Initiated Emergency Contraceptives on Pregnancy and Abortion

The true impact of the health policy change authorizing pharmacist-initiated emergency contraceptives can be measured only by evaluating whether the program has increased overall access or has simply transferred emergency contraceptive prescriptions from physicians to pharmacists. Such an outcomes evaluation is currently underway in British Columbia using data from the PharmaNet prescription database.

The impact of pharmacist-initiated prescriptions on emergency contraceptive utilization can be estimated from the number of emergency contraceptives dispensed during the first year of the expanded access programs. In Washington, about 9000 women received emergency contraceptives in the first year, while in British Columbia, nearly 6200 women were provided with an emergency contraceptive agent by a pharmacist. The methodology outlined by Wells et al.[44] assumes that the pregnancy risk after unprotected intercourse is 10% and that emergency contraceptives are effective 75% of the time when using the Yuzpe regimen. Theoretically, pharmacist-initiated prescriptions would have prevented 675 unintended pregnancies in Washington and 465 unintended pregnancies in British Columbia during the first year of the programs. If approximately half of unintended pregnancies end in abortion,[56] then the Washington and British Columbia programs to expand access through community pharmacists may have prevented as many as 337 and 232 abortions, respectively. As the effectiveness of the progestogen-only emergency contraceptive pill is higher than that of the Yuzpe regimen,[20,21] and is being prescribed by pharmacists in both Washington and British Columbia, the potential reduction in the estimated number of abortions could be considered the lower bound. In Manchester, UK, about 1000 women accessed the program each month.[52] Since the group protocol uses only the progestogen-only product, approximately 1020 unintended pregnancies and 510 abortions may have been prevented during the first year. Similar UK pilot projects have also been very successful.[52]

Equally important to the issue of the impact of pharmacist-initiated programs is the 42% of women in Washington State who claimed that they would have waited to see if they became pregnant, and the additional 16% who stated that they did not know what they would have done if they had not been able to obtain emergency contraception from a pharmacist.[44]

4. Challenges for Emergency Contraceptive-Related Research in the Future

Despite these extrapolated data on the impact of the pharmacist-initiated programs, various questions and challenges still remain to be addressed. These relate to multi-use oral contraceptive products provided as emergency contraceptives, direct and indirect adverse outcomes of the transfer to OTC provision, potential changes in access and availability, economic and societal implications of reimbursement strategies, the expanded role for pharmacists as a healthcare practitioner and the need for population-based outcomes research to evaluate the impact of these new programs.

4.1 Oral Contraceptives Provided for Emergency Contraception

The WHO noted in its 1995 consensus statement[1] that few products were specifically marketed for emergency contraceptive use, and that most methods involved use of routine contraceptives. Then in 1997, the *Federal Register*, the publication of the US FDA, announced that six specific regular birth control products were safe and effective for use as postcoital emergency contraception, and that 'the use of combined oral contraceptives for emergency contraception in the United States can only be estimated because they are not approved for this indication'.[36] The notice also stated that actual use of emergency contraceptives in the United Kingdom was much greater than the number of recorded prescriptions of dedicated products 'because providers have found it less expensive to provide tablets of identical drugs taken from products packaged as combined oral contraceptives'.[36] These comments highlight the difficulty of accurately evaluating the magnitude of emergency contraceptive use, when sales figures of a dedicated product have not been available. Now that progestogen-only agents are being specifically packaged for emergency contraceptive use, utilization will be easier to document with these products.

Ongoing use of the inexpensive, yet effective combination estrogen-progestogen products will continue to create methodological issues in differentiating between oral contraceptive and

emergency contraceptive use. Quantifying emergency contraceptive utilization at baseline prior to the initiation of an innovative pharmacist-initiated prescribing program or a regulatory switch to OTC status is essential when attempting to evaluate the impact of the new source of supply of these agents. While unmonitored changes in the mechanism for the provision of emergency contraceptives are occurring in different jurisdictions, areas that have the capability to carefully evaluate the impact have an important opportunity to contribute new knowledge on the ramifications of these health policy changes. In British Columbia, such a possibility is provided by the availability of a prescription database that records all prescriptions for residents in the province and has the capability of linking, in a confidential manner, the data from all medical and hospital services. Once emergency contraceptive products are transferred to OTC provision, lack of mandated dispensing records will mean that the opportunity to track individual patients in a confidential manner will be lost.

4.2 Issues Surrounding the Transfer from Prescription-Only to OTC Provision of Emergency Contraceptives

Considering the transfer of emergency contraceptives to OTC status implicitly assumes that there are no negative clinical consequences of widely available access to these agents. As clearly stated by Grimes et al.,[41] emergency contraceptives 'meet all the customary criteria for OTC use: low toxicity, no potential for overdose or addiction, no teratogenicity, no need for medical screening, self-identification of the need, uniform dosage, and no important drug interactions'. Nevertheless, there is the potential for serious long-term consequences of unsupervised distribution of OTC emergency contraceptives.

STIs are an established risk of unprotected intercourse. If undiagnosed and untreated, potentially serious complications may result, including chronic pelvic pain, infertility and ectopic pregnancy.[57,58] Physician guidelines and position statements suggest that counselling on safer sex, STIs and regular contraception are a routine follow-up clinical practice component of requests for emergency contraception,[59] and that testing for STIs should be done 1 to 2 weeks after exposure if it is of concern.[37] Training programs for pharmacist-initiated prescribing of emergency contraceptives stress the importance of the pharmacist giving targeted sexual health advice and referring a woman to a physician or an STI screening clinic for diagnosis and treatment if there is a risk of infection.[60-62] With the transfer of emergency contraceptives in the United Kingdom to OTC status, concern has been expressed over decreased detection and risk reduction for STIs.[63,64] Limited referrals for testing may result in subsequent societal and individual costs for infertility and further dissemination of STIs.[65] A potential research opportunity using the varied pharmacist-initiated programs would be to investigate the proportion of women who actually follow up on pharmacist-provided referrals for screening for STIs, and compare this to the screening rates of physicians. With the development of easy-to-administer chlamydia screening tests it may also be possible in future to provide some STI testing through community pharmacies.

Sexual assault victims obtaining emergency contraceptives in an OTC setting, rather than in a structured pharmacist-patient interview setting, may not as feel comfortable disclosing to the pharmacist that they have been assaulted. Consequently, they may not be referred to a specialized sexual assault support program in a timely manner, which may potentially result in long-term psychosocial sequelae.[66] Sexual assault victims may also be at risk of STIs, and reduced reporting of these incidents may result in women at risk not being offered the preventive treatment they require.[67]

Women are advised to begin a regular method of birth control as soon as possible after using emergency contraceptives, as the effectiveness of routine contraceptive agents is higher.[36] A large baseline study of emergency contraceptive prescribing by physicians in the United Kingdom demonstrated that more than 70% of women started on regular contraceptives for the first time within 1 year of emergency contraceptive use.[68] No information is yet available comparing the incidence of regular contraceptive use following physician- and pharmacist-prescribed emergency contraceptives, although an evaluation using the British Columbia prescription database is currently underway. As community pharmacists are advised to recommend follow-up contraceptive care as part of their training for pharmacist-initiated emergency contraception, it is possible that improved access to advice from a health professional may increase the likelihood of clients seeking follow-up care. Conversely, concern that women without regular physicians may use community pharmacies as the source of OTC emergency contraceptives, and then not be referred for follow-up contraceptive care, is a potential negative consequence of the switch to OTC status.

It is possible that the efficacy of oral and emergency contraceptives may be reduced by the concomitant use of liver enzyme-inducing medications such as phenytoin, carbamazepine, rifampicin (rifampin) and possibly St. John's Wort.[69-71] Although there is no definitive evidence on how the dose of emergency contraceptives should be adjusted, the theoretical possibility has led some organizations to recommend increasing the dose of emergency contraceptives when a potential interaction is present.[53,59,72,73] Further research needs to be done in this area. When data substantiating the need for dosage modification be-

comes available, labelling changes and direct pharmacist-patient consultations will be advisable to highlight the need for dose alteration.[41]

4.3 Potential Changes in Access and Availability

The provision of emergency contraceptives by community pharmacists has been encouraged as a means of enhancing timely access through extended pharmacy hours, extensive locations, and elimination of the need for a medical appointment.[27] However, there is concern that such an alternate service delivery program may not be actually enhancing access, just availability. Thus, it is paradoxical that OTC provision may decrease access for women for whom emergency contraceptives are free when a prescription is written by a physician, but who would need to pay the entire cost should the product no longer be covered by government or third-party insurers. Sales figures of OTC Levonelle® in the UK suggest that the majority of women who obtain the emergency contraceptive are working and aged between 25 to 35 years.[74] In the article, Dr Marianne Parry is quoted as saying 'The morning after pill is too expensive for young women'.[74] Thus, for the individual, it is possible that there would be an increased cost and disenfranchisement. Many Primary Care Trusts in the United Kingdom have now begun to introduce patient group directives for free supply of emergency contraceptives from community pharmacies for women aged under 20 years to reduce teenage pregnancies.[75]

4.4 Economic and Societal Implications of Reimbursement Strategies

Emergency contraception reduces expenditures by preventing unintended pregnancies, and in both the American and Canadian healthcare systems is cost saving when used for immediate use or when provided for later use should unprotected intercourse occur.[76,77] Using the Washington model of collaborative agreement, the provision of emergency contraceptives by a pharmacist rather than a physician reduced costs for both private and public payors.[49] This recent study reinforces the comments of Ellertson et al. 3 years earlier: 'from the perspective of cost containment, it is wasteful to require physician involvement in use of such a simple, safe, and effective product'.[78] Should OTC status not be approved by regulatory bodies, then as Ellertson indicated, 'allowing women to obtain ECPs (emergency contraceptive pills) from pharmacists, rather than OTC, might be a workable compromise'.[78]

Emergency contraceptives reduce unintended pregnancies and are cost saving. Decision-makers in publicly and privately supported healthcare systems need to become informed of the societal consequences of their decisions. For example, they need to consider whether it is more effective to pay for emergency contraceptives and necessary counselling at the present time, or to pay in the future for abortions, unwanted births, and cases of STIs that were not referred and detected early.

4.5 Expanded Role for Pharmacists as a Valuable Health Care Resource

The evolution of patient-centered pharmacy practice has resulted in pharmacists being increasingly recognized as a valuable healthcare resource. Support for the expanded role of pharmacists to improve availability of emergency contraceptives has come from a broad base of multidisciplinary professional organizations.[37,46] As described by Hutchings et al.,[46] the goal of the collaborative agreement model of pharmacist-initiated prescribing 'is to enhance patient care by: increasing access to primary healthcare in a cost-effective manner, reducing drug-related problems, improving therapeutic outcomes, and using resources most effectively'. If negative clinical consequences (e.g. increased incidence of STIs, reduced referrals) of OTC emergency contraceptive sales are demonstrated to be important enough, then this may further enhance the importance of a pharmacist as an intermediary to refer patients to community-based healthcare screening and treatment programs.

4.6 Need for Population-Based Outcomes Research to Evaluate Program Impact

Despite worldwide advances in enhancing access to emergency contraceptives, no population-based studies to date have investigated the impact of an expanded access program on changes in emergency contraceptive utilization patterns or on pregnancy and abortion rates. Few jurisdictions have linked databases that include comprehensive prescription, medical and hospital services for all residents in the population of interest. More than 900 000 women of childbearing age reside in British Columbia and have a unique patient identifier. Their inclusion in the interlinked HealthNet databases provides researchers with an unparalleled opportunity to evaluate the overall impact of this unique healthcare policy initiative on equitable access by all segments of the population. Preliminary work to develop a theoretical model to forecast post-intervention changes in pregnancy and abortion rates, to establish baseline levels of physician-prescribed emergency contraceptives, and to monitor the initial uptake of the pharmacist-initiated expanded access program by our multidisciplinary research team will provide new insights into the health policy implications of pharmacist-initiated emergency contraceptives in a monitored setting.

4.7 What Are the Most Promising Practical Questions for Future Research?

The diverse mechanisms of pharmacist-initiated programs described in section 2 provide the opportunity to explore the public health implications of utilizing pharmacists to prescribe emergency contraceptive agents. These questions include:

- Do pharmacist-initiated emergency contraceptive prescriptions represent expanded access to emergency contraceptives or simply a transfer of the prescribing of these agents from physicians to pharmacists?
- If overall utilization is increased, what is the anticipated impact on pregnancy and abortion rates?
- If the distribution of OTC emergency contraceptives expands into new jurisdictions, what will be the role of pharmacists in directly interacting with the emergency contraceptive user?
- What are some of the potential drawbacks of pharmacist-provided emergency contraceptives, and how can those issues be addressed?
- Of the various mechanisms of pharmacist-initiated emergency contraceptives, which process provides the most effective way of expanding access and availability?
- In those countries that have transferred emergency contraceptives from prescription-only to OTC status, what are the various roles of pharmacists, and have unintentional barriers to access occurred that have reduced the availability for certain populations, such as teenagers and those with restricted discretionary income?

5. Conclusions

Innovative new initiatives using a variety of regulatory mechanisms have recently been developed to allow pharmacists to prescribe and sell emergency contraceptives. These pharmacist-initiated programs offer the opportunity to investigate the impact and public health implications of utilizing pharmacists to provide emergency contraceptive agents. Ongoing prospective research will provide health policy makers at the national and international levels with the evidence necessary to make informed decisions regarding the preferred pharmacist-initiated mechanism of expanding availability of emergency contraceptives. Ultimately, the goal of all emergency contraceptive healthcare initiatives is to reduce the burden on individuals and society of unintended pregnancy and abortion.

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