

PRN OPINION PAPER

Changing Oral Contraceptives from Prescription to Over-the-Counter Status: An Opinion Statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy

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Addressing the issue of unintended pregnancy is a national priority. One proposed strategy to reduce unintended pregnancy is to improve access to oral contraceptives by changing them to over-the-counter (OTC) status. Existing data indicate that oral contraceptives meet safety criteria required of OTC products. Available literature demonstrates that women can self-screen for contraindications to oral contraceptives and can do this as well as clinicians, and experience with OTC emergency contraception suggests that OTC oral contraceptives would not increase sexual risk-taking behavior. Women support OTC access to oral contraceptives, but express an interest in accessing pharmacist counseling. On the basis of these data, the Women's Health Practice and Research Network of the American College of Clinical Pharmacy supports changing oral contraceptives to OTC status under two conditions: that they are sold where a pharmacist is on duty and that there are mechanisms in place to cover OTC contraceptives through Medicaid. Future research should address the issues of out-of-pocket costs to individuals, label-comprehension studies, and models for pharmacist reimbursement for time spent counseling on contraception.

Key Words: oral contraceptives, nonprescription drugs, over-the-counter status, OTC, delivery of health care, community pharmacy, collaborative drug therapy.

(*Pharmacotherapy* 2011;31(4):424-437)

Preventing unintended pregnancy continues to be a major public health focus in the United States, where almost half of all pregnancies are unintended.¹ Unintended pregnancies are associated with poor health outcomes for infants and mothers and have negative social and economic implications for society as a whole. Women experiencing an unintended pregnancy are less likely to seek prenatal care in the first trimester, more likely to drink alcohol and smoke during pregnancy, less likely to breastfeed, and

more likely to experience depression.^{2,3} Children born to women who did not intend to become pregnant are more likely to be low birth weight and small for gestational age, are at an increased risk for child abuse, and have fewer developmental resources available such as positive interaction with their mothers or opportunities for skill development.²⁻⁴ Unintended pregnancy is also expensive, with direct medical costs estimated to be \$5 billion in 2002.⁵ Teen pregnancies, of which 81% are unintended, cost

tax payers \$9.1 billion in direct and indirect costs.⁶

Addressing unintended pregnancy is a national priority. Healthy People 2010 set the benchmark that 70% of all pregnancies in the United States would be planned by 2010 and cites increasing contraception use as one strategy to achieve this goal.⁷ In their 2009 report on priorities for comparative research, the Institute of Medicine specifically called for the evaluation of “innovative strategies for preventing unintended pregnancies,” including “over-the-counter (OTC) access to oral contraceptives or other hormonal methods.”⁸

The call for OTC availability of oral contraceptives is not new; as early as 1993, the United States Food and Drug Administration (FDA) scheduled a meeting of the Fertility and Maternal Health Drugs Advisory Committee to address the question. The meeting was canceled and never rescheduled, partly due to opposition from organizations such as Public Citizen, the National Women’s Health Network, and some physicians and other family planning providers.⁹ Levonorgestrel (Plan B; Duramed Pharmaceuticals, Cincinnati, OH) was approved for emergency contraception in 2006, making it the first hormonal contraceptive with OTC availability.¹⁰ With the success of the prescription-to-OTC switch of levonorgestrel and the new recognition by the Institute of Medicine, advocates are once more evaluating the possibility of changing traditional oral contraceptives (including combined estrogen-progestin and progestin only) to OTC status. (The FDA approved ulipristal

acetate, a progestin agonist-antagonist, as a prescription-only emergency contraceptive in August 2010 after approval by the European Medicines Agency in March 2009.^{11,12} Because of the recent approval of ulipristal and its limited postmarketing surveillance data, this article pertains only to estrogen-progestin and progestin-only oral contraceptives.)

The pharmacy community has remained relatively quiet throughout the oral contraceptive prescription-to-OTC debate, despite pharmacists playing an increasing role in improving access to contraception and other public health initiatives.^{13–15} As pharmacists expand their clinical role in women’s health, it is important for pharmacists to contribute to policy debates affecting access to contraception. Pharmacists bring a unique perspective to the OTC debate with their understanding of access to contraception in the community setting and their role in counseling and educating consumers about both prescription and nonprescription contraceptives. In this article, we review the regulatory requirements around OTC approval, examine the safety data on direct access to oral contraceptives, discuss policy implications of a prescription-to-OTC switch, and provide policy recommendations on changing oral contraceptives to OTC status.

Regulatory Access to Drugs in the United States

Currently, the FDA classifies drugs as either OTC or prescription only. Prescription-only drugs can be accessed directly from a licensed prescriber, from a pharmacist with a prescription issued by a licensed prescriber, or directly from a pharmacist through collaborative drug therapy. The OTC products are available without a prescription and can be further defined to include behind-the-counter (BTC) products (Table 1).

Pharmacy Access

Drugs can also be accessed directly from a pharmacist with prescriptive authority, a practice known as pharmacy access. The most common form of prescriptive authority is through collaborative drug therapy agreements or protocols that require a prescription be issued by the pharmacist. Under these agreements, a pharmacist may voluntarily enter a collaborative protocol with an authorized prescriber or practice under a statewide protocol. The pharmacist is then responsible for properly

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This article represents the opinion of the Women’s Health Practice and Research Network of the American College of Clinical Pharmacy (ACCP). It does not necessarily represent an official ACCP commentary, guideline, or statement of policy or position.

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Table 1. Description of Direct Pharmacy Access Options

Type of Access	Description
Prescription	Requires a prescription from a licensed prescriber, upon which the drug can be dispensed by a pharmacist or directly from the prescriber
Pharmacy access	Requires a prescription, which can be issued directly by a pharmacist with prescriptive authority, most commonly through a collaborative drug therapy agreement or protocol; authority can apply to a single drug, a drug class, or a specific disease state (can be general or patient-specific disease state)
Behind-the-counter ^a	Over-the-counter access with restrictions such as age, quantity, or location of sale (e.g., emergency contraception, nicotine replacement, pseudoephedrine)
Over-the-counter	Available without a prescription at any location with no restrictions

^aNo true behind-the-counter classification exists in the United States.

screening patients, initiating therapy, and counseling the patient on correct use of the drug before dispensing it directly to the patient at the pharmacy.

Behind-the-Counter Access

Behind-the-counter drugs have OTC status and do not require a prescription. It is important to note that there is no official BTC designation in the United States, but because certain drugs have additional restrictions on their sale, including location of sale, minimum age of purchase, proof of identity, and maximum quantities, there exists a *de facto* BTC category. For example, levonorgestrel emergency contraceptive has OTC access only for those aged 17 years or older and must be sold from a licensed pharmacy.

Over-the-Counter Access

Over-the-counter drugs are available without a prescription. As classified by the FDA, OTC drugs generally have these characteristics: their benefits outweigh their risks, their potential for misuse and abuse is low, the consumer can use them for self-diagnosed conditions, they can be adequately labeled by the manufacturer, and health practitioners are not needed for safe and effective use. Both the Durham-Humphrey and Kefauver-Harris amendments to the Federal Food, Drug, and Cosmetic Act establish regulatory requirements for drugs to have OTC designation. The Durham-Humphrey amendment states that only non-habit-forming drugs that can be used safely by following a package insert can have OTC designation.¹⁶ To meet these requirements, patients must be able to read and interpret the package labeling in order to self-diagnose, recognize contraindications, and prevent drug interactions. The Kefauver-Harris amendment further states that a drug must be effective when used without medical supervision.¹⁶ Because oral

contraceptives are not habit forming and self-diagnosis is a matter of personal choice and prevention rather than a medical diagnosis, we focus on data surrounding the safety requirements. Over-the-counter drugs can be purchased from any venue and are not restricted in any way.

Safety, Screening, and Counseling

Guidance regarding medical eligibility criteria for oral contraceptives has been published by the World Health Organization ([WHO] Appendix 1^{17, 18}) and is used by several countries that provide oral contraceptives to women without a prescription, including Kuwait and Hong Kong (special administrative region of China) and by countries using community-based distribution programs to provide oral contraceptives.^{19, 20} Studies in the United States and Mexico have evaluated women's ability to self-screen for these contraindications, demonstrating feasibility of OTC availability in the United States.

Domestic Studies

It has been demonstrated that women can successfully determine personal candidacy for hormonal contraceptives. A 2006 study of 392 women in Washington found that women who were asked to complete a 20-item self-administered questionnaire based on WHO medical eligibility for using oral contraceptives had 96% agreement with their health care provider's (advanced registered nurse practitioner) same-day evaluation.²¹ These reproductive-aged women were more likely to identify contraindications than were their providers, resulting in appropriate use of a progestin-only method by 97% of participants and appropriate use of a combination method by 95%.²¹ This study was limited, as many of the patients had been using oral contraceptives before this visit. These women were more likely to be healthy, previously

screened, and not have the range of medical risks potentially found in the general population.

In 2008, a Texas study followed a similar protocol by using a self-administered survey given to 1271 women, followed by screening that included measuring blood pressure by a nurse practitioner, to identify WHO medical contraindications to combined oral contraceptives.²² The authors found that 6.6% of women whose surveys indicated candidacy for combined oral contraceptives had contraindications; this is similar to an evaluation of National Health Examination Survey data, which showed that 6% of women using combined oral contraceptives had contraindications.²³ In the Texas study, women aged 35–49 years were more likely to incorrectly assess their eligibility for combined oral contraceptives compared with younger women (aged 18–34 yrs). When the results of providers' and self-screening evaluations were compared, women were more likely to inaccurately eliminate themselves from candidacy for combined oral contraceptives ($p=0.001$). Limitations to this study involved the nurse practitioners' screening process, which may have been more rigorous than a typical evaluation of a woman seeking combined oral contraceptives, and the inexperience of the nurse practitioners in prescribing these drugs, leading them to deem the patient had contraindications if they were not confident that a combined oral contraceptive was safe in a particular condition.

As access to contraception has become increasingly important, the use of the Internet as an education resource has risen. An Oregon study compared women's knowledge of contraindications and adverse effects of oral contraceptives after obtaining the drug through an online program (161 women) or in person at the clinic (243 women).²⁴ The two groups had similar scores, although in some areas, the online group showed superior knowledge. The authors concluded that women who seek oral contraceptives outside of a traditional health care setting are just as knowledgeable about contraindications and adverse events as women seen in a clinic.

In addition to women's ability to properly self-screen for contraindications, there is some concern that increased access to contraception will increase sexual risk-taking behavior, a debate that figured prominently in the prescription-to-OTC switch of emergency contraceptives, or will decrease regular screenings for conditions such as cervical and breast cancer or sexually trans-

mitted diseases. Current literature dispels this concern. The OTC levonorgestrel emergency contraceptive has been shown to benefit patients by increasing their access to the product without negatively affecting their regular contraceptive use or sexual risk-taking behavior (e.g., not using condoms, increased number of sexual partners).^{25–27}

Another concern with OTC access to contraception is that women will forgo needed preventive care. A 2004 survey of 811 U.S. women alleviates this fear, as researchers found that 88% of women not using contraception in the last 2 years had still obtained a Pap test, illustrating that even if women are not seeking contraception they will still obtain recommended preventive care.²⁸ In addition, the American College of Obstetricians and Gynecologists recently updated cervical screening guidelines and now recommends the first cervical screening for cancer begin at age 21 years, regardless of onset of sexual intercourse.²⁹ Screening should occur only every 2 years until the age of 30 years and, with no other risk factors present, every 3 years thereafter. Annual examinations are still appropriate to rule out sexually transmitted diseases and to provide other counseling, but screening patients for cervical and breast cancer or sexually transmitted diseases should have no impact on the decision to initiate hormonal contraception.^{29, 30}

International Studies

Data from countries where oral contraceptives are available without a prescription provide insight into the actual behaviors of women with access to OTC oral contraceptives. A 1987 study conducted in Mexico compared 102 women who obtained their oral contraceptive through a community-based distribution program as a nonprescription item with 135 women who did not use the community-based distribution program but obtained their oral contraceptives from other sources, including pharmacies, clinics, and private physicians. Of those not using the community-based distribution program, 71 had been examined for contraindications to oral contraceptive use and 64 had not ever been examined for contraindications.³¹ All patients were interviewed by the nurse to identify contraindications. Afterward, the nurses conducted subjective and objective assessments to validate screening questions. A significant proportion (73.2%) of the non-community-based distribution group who had ever received an examination before receiving oral contraceptives had also

obtained oral contraceptives through a pharmacy without a prescription. The patient's self-reported health conditions (hypertension, hyperglycemia, heart disease, liver disease, and anemia) were similar to the nurse's diagnoses for all three groups (community-based distribution, non-community-based distribution ever examined, and non-community-based distribution never examined). A major limitation to this study was the identification of certain health conditions such as anemia, which was done through observation of eyelid paleness during the home visit rather than by laboratory analyses. Although specific contraindication rates were not provided, based on the self-reported health conditions of women receiving and those not receiving a medical examination before starting an oral contraceptive, this study demonstrated that the patients had the ability similar to that of the nurse to identify potential health issues related to contraindications.

Similarly, another group of investigators analyzed the presence of contraindications in current users of oral contraceptives when obtained through either a clinic or pharmacy.¹⁹ This study used data from the 2000 Mexican National Health Survey, which included a blood pressure measurement. A total of 1246 women aged 20–49 years reported current use of oral contraceptives; however, 4% of the patients obtained their oral contraceptive from an unknown source and were excluded from the analysis. The remaining patients received their oral contraceptive from either a clinic (56%) or pharmacy (40%). Only smoking and hypertension were included as absolute contraindications. Overall, 2% of all users and 4% of users older than 35 years had these absolute contraindications for oral contraceptive use. Patients older than 35 years were less likely to recognize contraindications. However, no significant difference in the frequency of contraindications was found between patients obtaining their oral contraceptive from a clinic versus a pharmacy (1.8% vs 2.0%), and patients who obtained their contraceptive from a pharmacy were as likely as clinic patients to correctly self-identify contraindications of smoking and hypertension. This study was limited by the use of laymen for screening and by only including smoking and hypertension as contraindications.

Counseling and Adherence

One potential benefit of a prescription require-

ment is the added interaction with a health care professional to promote adherence and conduct routine preventive screening. Studies examining the role of counseling on adherence to contraception have found mixed results.

A study conducted in Kuwait assessed if there was a difference in baseline characteristics between women who consulted a physician before obtaining oral contraceptives and women who bought them directly from the pharmacy or clinic without a physician consultation.³² The study surveyed 1502 women of whom 811 (54%) had used oral contraceptives as their first method of contraception, and 605 (75%) of these 811 women consulted with a physician before starting an oral contraceptive. A higher percentage of women from urban areas did not consult a physician before the first use of oral contraceptives. Average duration of first time oral contraceptive use among recent oral contraceptive users (within 5 yrs before survey) was 13.7 months and was significantly increased with increasing age of the woman and larger family size, but was not affected by physician consultation before starting an oral contraceptive.

A 2006 Cochrane review evaluated the effectiveness of contraceptive counseling with regard to adherence and continuation of hormonal contraceptives.³³ Six studies were included for review and evaluated interventions such as group motivation, peer counseling interventions, structured audiovisual messages, written and videotape information, peer counseling versus nurse counseling, and intensive reminders versus regular appointment cards. Among these counseling strategies, no significant differences were noted between groups. However, it is important to note that the trials were small and had a high loss-to-follow-up rate. The strategies may be limited to the population being studied.

Another review had similar findings to those of the Cochrane review with regard to identifying an appropriate contraception counseling strategy to decrease unintended pregnancies.³⁴ Both the Cochrane review and this review illustrate that contraceptive counseling by a health care professional does not necessarily improve adherence, indicating that a potential lack of counseling with OTC access to oral contraceptives should not result in worse adherence due to lack of interaction with a health professional.

Policy Issue Considerations

The OTC availability of oral contraceptives in

the United States may lead to increased access and patient use of regular contraception, but it is important to examine the impact on access that other prescription-to-OTC switches have had. The levonorgestrel emergency contraceptive provides an important comparator to examine the potential issues associated with OTC oral contraceptive access. These issues include the effects of OTC availability on access, contraceptive or sexual risk-taking behavior, cost to individuals and society, women's attitudes, and pharmacists' and prescribers' attitudes toward a prescription-to-OTC switch.

Does OTC Availability Translate to Increased Access?

One group of authors showed the benefit of greater availability of levonorgestrel emergency contraceptives with OTC status.³⁵ Pharmacies in Atlanta, Philadelphia, and Boston were surveyed regarding their ability to provide levonorgestrel emergency contraception to patients within 24 hours in 2005 and again in 2007 after the switch of levonorgestrel from prescription to OTC status. The percentage of pharmacies unable to dispense levonorgestrel emergency contraception within 24 hours decreased significantly between 2005 and 2007 (22% vs 8%, $p < 0.0001$). A similar study by another group surveyed 239 pharmacies in Ontario to assess the impact on access after the switch of levonorgestrel emergency contraception to OTC status.³⁶ Surveys were conducted 1 month before and 14–17 months after the prescription-to-OTC switch with a 79% and 70% response rate, respectively. The number of pharmacies with levonorgestrel emergency contraceptives in stock increased from 78% to 92% after the prescription-to-OTC switch. Using 1999 and 2004 French national survey data, a group of authors found that the use of levonorgestrel emergency contraceptive increased with pharmacy access (from 9.8% in 1999 to 16.9% in 2004, $p < 0.001$).³⁷

Improved availability and access to levonorgestrel were found to lead to increased patient awareness of emergency contraception, but this did not translate into increased use.³⁸ Given the results of these studies from three different countries,^{35–38} an OTC designation for oral contraceptives may improve women's access to and, in some cases, use of oral contraceptives while also raising their awareness of other options for contraception.

What Are the Financial Implications of a Prescription-to-OTC Switch?

With increased access through OTC availability, the effects on patient and societal costs are important considerations. Although OTC status may increase availability, there are concerns that the out-of-pocket cost of the OTC product may be a barrier to patients; nationwide, the cost of emergency contraception ranges from \$25–45/treatment.⁵ It is also unclear whether private insurance companies or Medicaid would cover OTC contraceptives; currently only nine states cover OTC emergency contraceptives.^{39, 40} Furthermore, a move to OTC status may result in an increase in price for comparable prescription products. For example, when the second-generation antihistamine loratadine moved from prescription to OTC status, WellPoint Healthcare, Inc. (Indianapolis, IN) encouraged use of the OTC product by increasing the copayments of the remaining prescription-only second-generation antihistamines.⁴¹

Contrary to the loratadine example, there is the potential that insurance coverage for OTC agents may increase as more drugs receive OTC status and third-party payers continue to promote patient self-care. Between 1998 and 1999, the percentage of health maintenance organizations covering OTC drugs doubled from 6.6% to 12.3%.⁴¹ There may also be a cost savings for third party coverage of OTC drugs. A state health plan in Arkansas reportedly saved 38% in proton pump inhibitor costs over 15 months after allowing coverage for OTC omeprazole.⁴²

Although the cost implications of a prescription-to-OTC switch to individual women are not well documented in the literature, the benefits to society have been. One study compared the costs of a pregnancy to the costs of various forms of contraception. All contraceptive methods were considered cost-effective. Contraceptive methods saved more in public expenditures for unintended pregnancies than they cost to provide and oral contraceptives would save over \$4 for every \$1 spent.⁴³ Potential cost benefits would include fewer clinic visit costs for patients in addition to reducing the costs of unintended pregnancies. Another study analyzed the potential benefits of OTC availability versus the possible costs and reported a net societal benefit of over \$2 billion.⁴⁴ The author suggests psychological benefits of reduced anxiety from unintended pregnancy, reduced stress from avoiding a pelvic exami-

nation, and increased confidence in using a reliable method of contraception in addition to the possible health benefits of using OTC oral contraceptives.⁴⁴

How Do Women Feel About OTC Access or Access from a Pharmacist?

A 2004 U.S. national telephone survey of 811 women aged 18–44 years examined their readiness and comfort level of obtaining oral contraceptives, the ring, the patch, or emergency contraceptives directly from the pharmacist without a prior prescription.²⁸ Awareness of oral contraceptives was high across all ethnicity groups (99%). The three main considerations affecting contraceptive choice were convenience, simplicity, and affordability. More than half (54%) chose their contraceptive method because it did not require a prescription. When asked about pharmacy access to contraceptives, 76% of women reported they would personally benefit if a clinic visit was not required before filling their prescription, with 68% of women saying they would use pharmacy access to obtain hormonal contraception if available. Of the women not currently using contraception, 47% of uninsured women and 40% of low-income women stated they would begin using it if pharmacy access was available. The role of pharmacists factored prominently into women's support of OTC access to hormonal contraception; support for pharmacy access to hormonal contraception dropped from 63% with pharmacist counseling to 43% when screening by a pharmacist was not mentioned by the interviewer. Women also believed the pharmacist should provide method instruction (75%), provide screening and counseling regarding method (46%), and be available to answer questions (24%).

Similar results were found by another group of authors in their focus groups and in-depth interviews conducted among low-income women in Massachusetts.⁴⁵ Most women thought oral contraceptives were safe enough for OTC access, but had concerns about safety, cost, and the need for contraceptive counseling. Some suggestions from women to implement the prescription-to-OTC switch included requiring insurance companies to cover OTC products, limiting minors' access, and placing the products behind the counter.

Latinas have been identified as a population with large numbers of unintended pregnancies. One study surveyed a Latina population of 794

women at risk for unintended pregnancy in Texas in order to assess perceptions of safety of oral contraceptives and the effect of OTC status on their likelihood to use oral contraceptives.⁴⁶ Sixty percent of women surveyed who were not currently using contraception indicated that they would be more likely to use oral contraceptives if the drugs had OTC availability. The authors point out that this is especially interesting given that many women were originally from Mexico where OTC oral contraceptives are available.

The impact of a collaborative drug therapy protocol to screen and counsel women for use of hormonal contraceptives was evaluated in a community setting.¹³ After 214 women were enrolled, 195 women (91%) were prescribed hormonal contraceptives as the intervention group and were followed for 12 months. Nearly all respondents who completed the 12-month follow-up (123 [96.8%] of 127) were satisfied with the program, stating that they felt comfortable receiving contraceptives from the pharmacist, were comfortable asking the pharmacist questions, and would recommend a friend to the pharmacist.

Patients were also satisfied receiving depot medroxyprogesterone acetate (DPMA), another form of hormonal contraception, from pharmacists in California. In a 2-year demonstration that allowed established users of DPMA to obtain their reinjection from a pharmacist, patients considered the pharmacy service a valuable access option, and half of the DPMA users were willing to pay a set fee, up to \$10, for the pharmacy reinjection service.⁴⁷

How Do Pharmacists Feel About Providing Reproductive Health Services?

A national survey study of U.S. pharmacists practicing in community pharmacies as well as other settings was conducted in 2004–2005.¹⁴ Randomly selected members of the American Pharmacists Association received an electronic survey assessing their interest in, comfort with, and perceived barriers to providing hormonal contraception. Most expressed interest in providing pharmacy access to hormonal contraception (85%), and nearly all viewed it as an important public health issue (98%).¹⁴ Of the 15% not interested in providing pharmacy access to hormonal contraception, 88% cited lack of time and 58% noted personal or religious beliefs.

In California, 502 pharmacy students also indicated that they were interested in providing

reproductive health services in their future community pharmacy practices, particularly hormonal contraceptive services under statewide protocol (96%), providing preventive measures against sexually transmitted infections ([STIs] e.g., human papillomavirus vaccine [89%]) and STI treatment for the partners of patients presenting with valid STI prescriptions (88%; unpublished data, S. Rafie, Pharm.D., and S. Y. El-Ibiary, Pharm.D., 2007). Students felt strongly that this would be a valuable service for many women (93%) and projected that patients would benefit from improved access and advice (94%). Adequate pharmacist time, followed by lack of a private counseling area in the pharmacy, was considered extremely important in determining whether pharmacists could efficiently and effectively provide services (unpublished data, S. Rafie, Pharm.D., and S. Y. El-Ibiary, Pharm.D., 2007).

How Do Other Professional Organizations View the Issue?

Few organizations have position statements on oral contraceptive OTC availability. However, many organizations, including the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, rallied in support of switching levonorgestrel emergency contraceptive from prescription to OTC status, and their opinions will figure prominently into future debates.^{48, 49} Currently, only one organization has a published statement on OTC access to oral contraceptives. The Reproductive Health Technologies Project Working Group on Oral Contraceptives affirms that oral contraceptives meet the FDA's criteria for OTC status and plans to research and resolve any potential negative aspects of a status change.⁵⁰

Pharmacist's Role in Providing Clinical Services in a Community Setting

Pharmacies, with their convenient locations and hours, are often used as first-line sources of medical advice, with pharmacists being viewed as trusted health care professionals.

In 2008, the National Campaign to Prevent Teen and Unplanned Pregnancy and the Association of Reproductive Health Professionals outlined key barriers to contraceptive use in youth and young adults. It was identified that practicing providers have insufficient opportunities for continuing education on advances in

contraceptive methods and changes in contraceptive protocols.⁵¹ One potential action step was to target pharmacists for continuing education, since pharmacists are often "gatekeepers" of emergency contraception and are authorized to prescribe in many states.

Pharmacists provide a variety of clinical services in the community setting including reproductive health services. Most notable is the provision of emergency contraception. A select group of states—Alaska, California, Hawaii, Massachusetts, Maine, New Hampshire, New Mexico, Vermont, and Washington—allow pharmacists to provide emergency contraception to women without a prior prescription.⁵² Procedures and protocols vary between states, such as in Hawaii where the minimum age to receive emergency contraception from a pharmacist is 14 years.

Other reproductive health services are available through pharmacists as well. Pharmacists' counseling on the proper use of condoms and transmission of human immunodeficiency virus (HIV) was highlighted in a San Francisco study, which reported that about 50% of pharmacists were accessible, knowledgeable, and willing to counsel on the use of condoms and prevention of STIs.⁵³ As previously mentioned, pharmacists in California provided contraceptive reinjections and pharmacists in Washington State provided hormonal contraception to women through collaborative drug therapy agreements, both in a community setting.^{13, 47} In the Washington study, patients completed a self-administered questionnaire reviewed by the pharmacist to determine if a contraceptive was appropriate for the woman.¹³ Pharmacists spent about 23 minutes/consultation (range 10–35 min), with pharmacists deviating from the protocol when prescribing oral contraceptives in seven cases. Contraception continuation rates at 6 and 12 months were approximately 80% and 70%, respectively, compared with 50% at 12 months reported in the literature.⁵⁴ Results from this study may serve as the precedent to develop similar reproductive services in other states.

Pharmacists are not only involved in providing reproductive health services, but are well positioned to provide other clinical services, such as smoking cessation counseling, immunizations, disease state education and management, and drug therapy management. The Asheville project is one example, where pharmacists in 12 community and hospital pharmacies provided

cardiovascular and cerebrovascular risk reduction education, long-term follow-up with scheduled counseling appointments, monitoring of drug therapy, and discussions with physicians.⁵⁵ Mean total cholesterol level, mean systolic and diastolic blood pressure, and the cerebrovascular event rate all decreased, showing the benefit of pharmacists as providers for disease state and drug management. Pharmacists also can serve as a screening provider for other serious conditions and make necessary referrals. In an Iowa study, pharmacists screened women older than 60 years for risk factors of osteoporosis.⁵⁶ Pharmacists provided education and risk assessment for 159 women. Of those, 53% were considered to be at moderate-to-high risk for osteoporosis and were referred to their physicians. Other studies have shown pharmacists to be beneficial in disease state and drug management for conditions such as HIV, depression, diabetes mellitus, and obesity.⁵⁷⁻⁶² The studies indicate the potential and ability of pharmacists to provide effective clinical services in the community setting.

Are Pharmacists Adequately Educated and Trained to Provide Hormonal Contraceptive Services?

As of 2006, all graduating pharmacists possess a doctor of pharmacy (Pharm.D.) degree. The Accreditation Council for Pharmacy Education (ACPE) has curricular requirements encompassing the various aspects of hormonal contraceptive service provision, including screening, prescribing, and monitoring. The ACPE mandates that the pharmacy college or school must ensure that graduates are competent to provide patient-centered care through the ability to design, implement, monitor, evaluate, and adjust pharmacy care plans; address health literacy, cultural diversity, and behavioral psychosocial issues; and promote the availability of effective health and disease prevention services and health policy. Of note, physical assessment is required content in the curricular core area of pharmacy practice.⁶³ Additional standards around women's health have been developed by the American Association of Colleges of Pharmacy (AACCP).

Training in school may not translate into comfort in providing reproductive health services in practice. One group of investigators found that pharmacists interested in providing pharmacy access to hormonal contraceptives reported comfort measuring blood pressure and weight, conducting medical history and risk assessment, counseling patients on method use, scheduling

patient follow-up, and assessing risk for STIs.¹⁴ Despite this comfort, pharmacists reported a need for additional training on various aspects of service provision, such as selecting the best method for each patient, identifying patients who are not candidates for hormonal contraception use, advising clients on preventive services (screening for STIs, cervical cancer, and breast cancer), risks and benefits of hormonal contraception, and general information about hormonal contraceptive options.

Pharmacy students in California expressed that they believe pharmacists are well trained and educated to provide orders and counseling on hormonal contraception (79%) and that provision of hormonal contraceptive services is within the pharmacist's scope of practice (89%; unpublished data, S. Rafie, Pharm.D., and S. Y. El-Ibiary, Pharm.D., 2007). Despite nearly two thirds of students (65%) reporting that they felt adequately educated by their pharmacy curricula to provide pharmacy access to hormonal contraception, they would like more education, particularly on appropriate product selection (79%) and switching between methods (77%; unpublished data, S. Rafie, Pharm.D., and S. Y. El-Ibiary, Pharm.D., 2007).

In a small qualitative study, 20 physicians and advanced-practice clinicians in California were interviewed regarding expanded access to hormonal contraceptives. Participants were divided in their perceptions of whether pharmacists are adequately trained to provide hormonal contraception screening, prescribing, and counseling. About one third thought pharmacists were adequately trained, and one quarter said pharmacists would be capable with more focused training. Nearly all reported feeling comfortable referring their patients to a pharmacist for hormonal contraceptive services under a pharmacy access model, and all said they would feel comfortable accepting referrals from pharmacists for patients who need additional care, such as STI screening and treatment, and pelvic examinations (unpublished data, S. Rafie, Pharm.D., and M. Haycock, Pharm.D., 2008-2009).

Recommendations

Over-the-Counter Status

The decision to change oral contraceptives to OTC status rests not just on the safety data, but also on an evaluation of the consequences this policy decision might have on access to contraception by the most vulnerable members of

our society. Therefore, the recommendations by the American College of Clinical Pharmacy (ACCP) Women's Health Practice and Research Network (PRN) include both those related to the prescription status of oral contraceptives and policies required to ensure access.

Studies in the United States and Mexico demonstrate that women are able to successfully self-screen for major contraindications to both combined oral contraceptives and progestin-only oral contraceptives, and that they do this as well as clinicians.^{21, 22, 31} The one contraindication that women cannot easily self-diagnose is hypertension. An estimated 13% of U.S. women are unaware that they are hypertensive, suggesting that some women who are considering combined oral contraception may benefit from consultation with a health care provider.⁶⁴ Community pharmacists have been screening for hypertension for over 2 decades and could provide this additional service.⁶⁵ In addition to the potential medical need for screening, women have also expressed an interest in having access to counseling.^{14, 45} One group concluded that a significant factor in women's acceptance of changing hormonal contraception to OTC status was the ability to be screened by or consult with a pharmacist.²⁸

Based on these data, the ACCP Women's Health PRN supports changing oral contraceptives (both combined and progestin only) to OTC status under the following circumstances:

- They are sold only in licensed pharmacies while a pharmacist is on duty.
- Legislation is in place at the national level to ensure that states covering prescription drug benefits for Medicaid recipients also cover oral contraceptives as an OTC product without a prescription.⁶⁶

The first restriction is similar to those placed during the approval of levonorgestrel emergency contraceptive, making oral contraceptives a de facto behind-the-counter product. It would ensure that women have access to a health care provider, but would not require them to consult with the pharmacist. As with all OTC consultations, pharmacists providing women with counseling on oral contraceptives should also assess whether a prescription method (such as long-acting reversible contraception) is more appropriate for the patient and provide appropriate referrals as necessary. The ACCP Women's Health PRN does not support age restrictions on the OTC oral contraceptives, as

state law regulates minors' access to reproductive health services.

The second stipulation strikes a balance between increasing access for all women and ensuring that low-income women can afford an OTC product. It would ensure that women in the lowest income bracket would have the same access as women in the wealthier brackets who can afford to pay out of pocket for an OTC product.

One potential mechanism to address insurance coverage of OTC products is through minimum coverage standards, either at the state or national level. For example, Massachusetts requires all residents to have health insurance that meets minimum creditable coverage standards, which includes prescription drug coverage, but does not include OTC products. If minimum creditable coverage was expanded to include OTC contraception, all insured women would have access to oral contraceptives regardless of their prescription status. The Patient Protection and Affordable Care Act has a similar provision that insurers cover "essential benefits,"⁶⁷ which ideally would include both prescription and OTC contraceptives.

The OTC option described will potentially result in fewer opportunities for patients to obtain counseling from a health care provider. One strategy to improve access to counseling would be through a pharmacy access model. Pharmacy access would ensure that all patients requesting oral contraceptives speak with a pharmacist and would potentially provide an avenue for reimbursement for these services. Although this option would promote access to counseling, it would not ensure all women uniform access to oral contraceptives as not all states have legislation in place allowing pharmacy access. Of states with collaborative drug therapy legislation, at least 20% have restrictions limiting or prohibiting pharmacy access programs in community settings.⁶⁸ An OTC model will provide more consistent access. The stipulation that oral contraceptives be sold in pharmacies with a licensed pharmacist on duty will ensure that women who want to speak with a pharmacist will have the opportunity to do so.

Future Research and Practice

Data are lacking regarding the individual cost implications of a prescription-to-OTC switch, and more research needs to be done in this area. These studies should specifically address the

impact of a potential switch on access for minority women and those in a low-income bracket. Label-comprehension studies, including postmarketing surveillance, to evaluate women's real-world use of screening guidelines are also needed.

For pharmacists to play a more active role in increasing access to contraception, innovative business models that allow a pharmacist to bill for their counseling time need to be developed. Effective models should allow pharmacists to bill for time spent counseling for both prescription and OTC products. The pharmacist's role in counseling and adherence to contraception should also continue to be evaluated. The physical structure of community pharmacies also needs to be evaluated to ensure that pharmacists can provide truly confidential counseling. Pharmacists are also encouraged to participate in existing pharmacy access programs currently available in their states and to form relationships with state and regional family planning programs. As the lay community and other health care providers begin to see pharmacists as a key ally in improving access to contraception, there will be more support for a BTC model.

Pharmacy organizations and pharmacists should also consider working with pharmaceutical manufacturers and encourage them to apply for OTC or BTC status of their products, and to provide support in the form of clinical research and testimony at regulatory hearings. Although pharmacists will be one component of a successful prescription-to-OTC switch, additional stakeholders will need to take action for this issue to move forward. These stakeholders include (but are not limited to) physicians and other family planning providers, pharmaceutical companies, medical and pharmacy boards, state and national legislators, and the FDA. All stakeholders are encouraged to help in achieving expanded access to oral contraceptives by supporting OTC or BTC access to oral contraceptives.

Education

More work needs to be done implementing reproductive health topics and experiential learning into pharmacy school curricula and providing continuing education for practicing pharmacists, including updates on new contraceptive methods and long-acting reversible methods. In addition to reproductive health, these programs should provide pharmacists with additional skills, such as screening for intimate

partner violence and providing services to minors, and ensure that pharmacists have adequate referral resources for comprehensive reproductive services. Evaluation of the implementation of the AACP Women's Health Education Standards among U.S. pharmacy schools should also be conducted to assess the current state of women's health curricula in pharmacy education. Forming partnerships between pharmacy organizations and other professional associations and government agencies, such as the Women's Health Curriculum Task Force, a partnership between the AACP and the FDA, will also be critical to advancing reproductive health in pharmacy education.

Conclusion

One strategy for addressing the nation's high rate of unintended pregnancy is to identify innovative ways to improve access to contraception. Changing oral contraceptives to OTC status is one such strategy. The data clearly indicate that women are able to self-screen for major contraindications to oral contraceptives, and community pharmacists could be a valuable resource for helping women make their decision about the appropriateness of hormonal contraception. We support changing oral contraceptives to OTC status with the condition that they are sold where a pharmacist is on duty. Less clear are the additional policies that need to be in place to ensure that a prescription-to-OTC switch improves access for all women, including those in low-income brackets and minority women. We have proposed one solution to ensure low-income women would have access to oral contraceptives in an OTC environment—that there are mechanisms in place to cover OTC contraceptives through Medicaid—but this solution only addresses women in the lowest income bracket and is not a universal solution. Given the recent high price of OTC emergency contraceptives, more research is needed on the additional out-of-pocket expenses women might face as a result of a prescription-to-OTC switch before any definitive action can be taken.

Acknowledgment

The authors thank Susan Berke Fogel, J.D., National Health Law Program, for her review of this manuscript and for contributing to the recommendations.

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Appendix 1. Eligibility Criteria for Contraceptive Use^{17, 18}

Criteria	Estrogen-Progestin Contraindications		Progestin-Only Contraindications	
	Relative	Absolute	Relative	Absolute
Breast cancer				
History and disease free for > 5 yrs	+			
Current breast cancer		+		+
Cerebrovascular				
Stroke		+		
Diabetes mellitus				
Diagnosed > 20 yrs ago	+			
Diabetes with end-organ damage	+			
Drug interactions				
Phenytoin	+		+	
Carbamazepine	+		+	
Barbiturates	+		+	
Primidone	+		+	
Topiramate	+		+	
Oxcarbazepine	+		+	
Lamotrigine (if using < 30 µg EE)	+			
Rifampin	+		+	
Ritonavir-boosted protease inhibitors (if using < 30 µg EE)	+		+	
Gallbladder disease				
Symptomatic gallstones without cholecystectomy	+			
Hormone-related gallstones	+			
Heart disease				
Ischemic heart disease		+		
Complicated valvular heart disease		+		
Hypertension				
Well-controlled blood pressure	+			
SBP 140–160 or DBP 90–100 mm Hg	+			
SBP > 160 or DBP > 100 mm Hg		+		
Hypertension + vascular disease		+		
Liver disease				
Mild cirrhosis	+			
Severe cirrhosis		+	+	
Tumors (benign or malignant)		+	+	
Active viral hepatitis		+		
Migraines				
Without aura and > 35 yrs old	+			
With aura (all ages)		+		
Surgery				
Major with prolonged immobility		+		
Thromboembolism				
DVT or PE (history of or active)		+	+	
			(active)	
DVT or PE on anticoagulation		+		
Systemic lupus erythematosus				
Positive antiphospholipid antibodies		+	+	
Severe thrombocytopenia			+	
			(initiating therapy)	
Tobacco use				
< 15 cigarettes/day and > 35 yrs old	+			
> 15 cigarettes/day and > 35 yrs old		+		

EE = ethinyl estradiol; SBP = systolic blood pressure; DBP = diastolic blood pressure; DVT = deep vein thrombosis; PE = pulmonary embolism.