The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 544 • December 2012

Committee on Gynecologic Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Over-the-Counter Access to Oral Contraceptives

ABSTRACT: Unintended pregnancy remains a major public health problem in the United States. Access and cost issues are common reasons why women either do not use contraception or have gaps in use. A potential way to improve contraceptive access and use, and possibly decrease unintended pregnancy rates, is to allow over-the-counter access to oral contraceptives (OCs). Screening for cervical cancer or sexually transmitted infections is not medically required to provide hormonal contraception. Concerns include payment for pharmacist services, payment for over-the-counter OCs by insurers, and the possibility of pharmacists inappropriately refusing to provide OCs. Weighing the risks versus the benefits based on currently available data, OCs should be available over-the-counter. Women should self-screen for most contraindications to OCs using checklists.

Unintended pregnancy remains a major public health problem in the United States. Over the past 20 years, the overall rate of unintended pregnancy has not changed and remains unacceptably high, accounting for approximately 50% of all pregnancies (1). The economic burden of unintended pregnancy has been recently estimated to cost taxpayers $11.1 billion dollars each year (2). According to the Institute of Medicine, women with unintended pregnancy are more likely to smoke or drink alcohol during pregnancy, have depression, experience domestic violence, and are less likely to obtain prenatal care or breastfeed. Short interpregnancy intervals have been associated with adverse neonatal outcomes, including low birth weight and prematurity, which increase the chances of children's health and developmental problems (3).

Many factors contribute to the high rate of unintended pregnancy. Access and cost issues are common reasons why women either do not use contraception or have gaps in use (4). Although oral contraceptives (OCs) are the most widely used reversible method of family planning in the United States (5), OC use is subject to problems with adherence and continuation, often due to logistics or practical issues (6, 7). A potential way to improve contraceptive access and use, and possibly decrease the unintended pregnancy rate, is to allow over-the-counter access to OCs.

Interest in Over-the-Counter Access

A 2004 national telephone survey of 811 women aged 18–44 years found that 68% of women at risk of unintended pregnancy would utilize pharmacy access for OCs, the contraceptive patch, the contraceptive vaginal ring, and emergency contraception. Also, 47% of uninsured women and 40% of low-income women who were not using OCs, the contraceptive patch, or the contraceptive vaginal ring said they would start using those methods if they were available from pharmacies without a prescription (8). In another survey of 1,271 women aged 18–49 years, 60% of women not currently using a highly effective contraceptive method said they would be more likely to use OCs if they were available over-the-counter (9). A national survey of 2,725 pharmacists found that 85% were interested in providing hormonal contraception, with 66% expressing concerns about reimbursement (10).

Safety of Over-the-Counter Medications

No drug or intervention is completely without risk of harm. For example, common nonsteroidal antiinflammatory drugs, such as aspirin, have documented adverse effects, including gastrointestinal bleeding. These effects may occur even at doses used for prophylaxis of cardiovascular disease (11). Additionally, over-the-counter use of acetaminophen is linked to serious liver damage (12). Safety concerns about OCs frequently focus on the increased risk of venous thromboembolism. However, it is important to understand that the rate of venous thromboembolism for OC users is extremely low (3–10.22/10,000 women-years) (13, 14) and to put this risk in context by recognizing the much greater

risk of venous thromboembolism during pregnancy (5–20/10,000 women-years) or in the postpartum period (40–65/10,000 women-years) (14). Overall, the consensus is that OC use is safe (15–17).

Ability of Nonphysicians to Screen for Contraindications

Despite the safety of OC use, one frequently cited concern regarding over-the-counter provision of OCs is the potential harm that could result if women with contraindications use them. However, several studies have shown that women can self-screen for contraindications. In one study that compared current family planning clients' self-assessment of contraindications with clinical assessment, 392 of the 399 participant (females aged 15–45 years) and health care provider pairs obtained agreement on medical eligibility criteria (greater than 90%) (18). Similar findings were seen in general populations of women, although in one study approximately 6% of the 1,271 women aged 18–49 years had unrecognized hypertension (19). Both studies showed that in cases of discrepancy, women were more likely to report contraindications than were health care providers. A study conducted in the United Kingdom replicated the findings that women take a more conservative approach compared with clinicians and also demonstrated that none of the 328 women studied would have incorrectly used OCs based on self-screening (20). Another study found that women obtaining OCs from pharmacies were no more likely to have contraindications than those who got OCs from a clinic (21). A study of women seeking to buy OCs online through a special program for patients of a clinic found that online participants (n=243) were as knowledgeable about contraindications and adverse events as women seen in the clinic (n=161) (22). It is acknowledged that the women with Internet access may not be comparable to the general population.

In contrast to the aforementioned studies, one U.S.-based cohort study found that women who obtained OCs over-the-counter in Mexican pharmacies were more likely to have relative contraindications rather than absolute contraindications (23) (see Box 1). At least one relative contraindication to OC use was found in 13% of the over-the-counter group versus 9% of the prescribed group (P=.006) but with similar frequencies of absolute contraindications (7% versus 5%, P=.162). However, women who purchased OCs over-the-counter in this study were not self-screened using any standardized process, and the demographics of patients (obese or lacking access to health maintenance services) may have affected the outcome.

Pharmacist provision (behind-the-counter access) of hormonal contraceptive methods also has been evaluated. In the Direct Access Study in Washington State, several pharmacists received specialized education in the provision of hormonal contraceptive methods and were authorized to provide hormonal contraception including, OCs, the contraceptive patch, and the contraceptive vaginal ring (24). Pharmacists successfully used checklists to identify women without contraindications to OCs according to the World Health Organization's Medical Eligibility Criteria for Contraceptive Use; blood pressure and body mass index also were measured (24). Continuation of use through 12 months was fairly high (70% of 127 women), although most women were continuing users (either currently using OCs or had used hormonal contraceptives in the past), and only 65% (127 of 195 women) completed the 12-month interview. Acceptability also was high, although most women had to pay out-of-pocket for the pharmacist evaluation because most insurance providers did not cover that service (24).

Box 1. Categories for Medical Eligibility Criteria for Contraceptive Use ⇦

1 = A condition for which there is no restriction for the use of the contraceptive method.

2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

U S. Medical Eligibility Criteria for Contraceptive Use, 2010. Centers for Disease Control and Prevention (CDC). MMWR Recomm Rep 2010;59(RR-4):1–86 [PubMed] [Full Text]

Contraceptive Adherence and Continuation

Other concerns about over-the-counter access include that women who choose to purchase OCs over-the-counter might be less adherent, less likely to continue their method, or less likely to choose more effective long-acting methods of contraception. However, efforts to improve use of long-acting methods of contraception should not preclude efforts to increase access to other methods. In one study, 68% of the women who might avail themselves to over-the-counter OCs reported not currently using any contraceptive method (8). Furthermore, continuation may be increased with better access. In a U.S. cohort study of approximately 1,000 women over 9 months, those who obtained OCs over-the-counter in Mexican pharmacies had slightly higher continuation rates (79.2%, P=.12) compared with those who obtained OCs in U.S. public clinics (74.9%, P=.12), although the increase was statistically insignificant (25).

Access to multiple pill packs at one time results in higher rates of continuation. In a 2011 randomized trial, investigators compared 6-month contraceptive continu-

ation rates among women who were dispensed three pill packs or seven pill packs. Participants who received seven pill packs had a higher 6-month rate continuation than participants who received three pill packs (51% compared with 35%, $P<.001$), and the effect was greater among participants younger than 18 years (49% compared with 12%, $P<.001$). Although not statistically significant, participants who received a prescription were less likely to continue OC use than those who received pill packs over-the-counter (26).

Use of Preventive Services

Another theoretic concern is that women who choose to purchase OCs over-the-counter will forgo screening and other preventive services. However, cervical cancer screening or sexually transmitted infection (STI) screening is not required for initiating OC use and should not be used as barriers to access (27, 28). The American College of Obstetricians and Gynecologists recommends an annual health assessment for every woman as a fundamental part of medical care (29). This visit also includes a discussion of a woman's reproductive health plan. She can review her health plan with her obstetrician–gynecologist on a periodic basis (30). This review provides an opportunity for the clinician to ask the patient what type or types of birth control she uses and to educate her about adverse effects of her chosen method and alternatives.

In a 2012 study, researchers compared the screening habits of U.S. women who had obtained their OCs from U.S. clinics with those who had obtained their OCs from Mexican pharmacies (31). Both groups reported high screening rates of Pap tests within the past 3 years (greater than 88%), ever having received STI testing (greater than 71%), and ever having had a clinical breast examination (greater than 88%), all higher than national screening proportions. Rates were slightly higher among those receiving OCs from clinics. Among those receiving OCs over-the-counter, the reasons given for no Pap testing included inconvenience, cost, and not knowing where to go to get screened (31). Currently, there are no long-term data of adverse health consequences for over-the-counter OC users.

Cost

It is possible that some women might be adversely affected by changing to over-the-counter OCs if they lose insurance coverage for their preferred contraceptive method. However, OCs are already a significant expense for many women. In a recent national survey, women, particularly young women and the uninsured, paid an average of $16 per pill pack, and many reported limits on the number of pill packs they could receive (32). Regardless, any plans to improve access to OCs by moving toward behind-the-counter or over-the-counter access should address issues of cost. The recent U.S. Department of Health and Human Services guidelines regarding women's preventive services will require new private health plans to cover without cost sharing all U.S. Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity (33). It remains to be seen how these guidelines will be implemented, and it should be noted that they do not apply to Medicaid. Pharmacy consultative services may incur additional costs.

Data From Developing Countries

Although the results of studies from developing countries may not be generalizable to a U.S. population, this information allows health care providers to examine the potential benefits and challenges of over-the-counter access to OCs in the United States. Some obstacles found in these studies include pharmacist refusal and a lack of counseling of patients on the proper use of OCs. (See Table 1 for additional data from developing countries.)

Conclusions and Recommendations

In the interest of increasing access to contraception, and based on the available data, the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice makes the following conclusions and recommendations:

- Weighing the risks versus the benefits based on currently available data, OCs should be available over-the-counter.
- Women should self-screen for most contraindications to OCs using checklists.
- There are concerns about payment for pharmacist services, payment for over-the-counter OCs by insurers, and the possibility of pharmacists inappropriately refusing to provide OCs.
- Screening for cervical cancer or STIs is not medically required to provide hormonal contraception.
- Continuation rates of OCs are higher in women who are provided with multiple pill packs at one time.

References

1. Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. Perspect Sex Reprod Health 2006;38:90–6. [PubMed] [Full Text] ⇦
2. Sonfield A, Kost K, Gold RB, Finer LB. The public costs of births resulting from unintended pregnancies: national and state-level estimates. Perspect Sex Reprod Health 2011; 43:94–102. [PubMed] [Full Text] ⇦
3. Institute of Medicine. The best intentions: unintended pregnancy and the well-being of children and families. Washington, DC: National Academy Press; 1995. ⇦
4. Frost JJ, Singh S, Finer LB. U.S. women's one-year contraceptive use patterns, 2004. Perspect Sex Reprod Health 2007;39:48–55. [PubMed] [Full Text] ⇦
5. Mosher WD, Jones J. Use of contraception in the United States: 1982–2008. Vital Health Stat 23 2010;(29):1–44. [PubMed] ⇦

Table 1. Data From Developing Countries ⇦

Country	Study	Conclusions
Jamaica	Chin-Quee DS, Cuthbertson C, Janowitz B. Over-the-counter pill provision: evidence from Jamaica. Stud Fam Plann 2006;37:99–110. [PubMed]	• Low-dose OCs have been available behind-the-counter since 1998. • Primary source of information of OCs was a doctor, nurse, or member of the clinic staff, not a pharmacist. • Access was restricted because of contraindications or younger age.
Kuwait	Shah MA, Shah NM, Al-Rahmani E, Behbehani J, Radovanovic Z. Over-the-counter use of oral contraceptives in Kuwait. Int J Gynaecol Obstet 2001;73:243–51. [PubMed] [Full Text]	• OCs were sold through pharmacies without prescription. • Few women were counseled about how to use OCs and few were counseled regarding side effects.
Mexico	Bailey J, Jimenez RA, Warren CW. Effect of supply source on oral contraceptive use in Mexico. Stud Fam Plann 1982;13:343–9. [PubMed]	• OCs are available over-the-counter in many pharmacies. • Pharmacy users had slightly higher continuation rates compared with other women but statistical significance is not reported.
Thailand	Ratanajamit C, Chongsuvivatwong V. Survey of knowledge and practice on oral contraceptive and emergency contraceptive pills of drugstore personnel in Hat Yai, Thailand. Pharmacoepidemiol Drug Saf 2001;10:149–56. [PubMed]	• Knowledge of how to obtain a proper medical history and counseling on the proper use and side effects of OCs was fair to good among both pharmacists and nonpharmacists. • Pharmacists were likely to have better knowledge overall than nonpharmacist staff members. • Secret shopper data reported that OCs were usually dispensed with little or no medical history or counseling.

Abbreviation: OC, oral contraceptive.

6. Smith JD, Oakley D. Why do women miss oral contraceptive pills? An analysis of women's self-described reasons for missed pills. J Midwifery Womens Health 2005;50:380–5. [PubMed] ⇦
7. Prepregnancy contraceptive use among teens with unintended pregnancies resulting in live births - Pregnancy Risk Assessment Monitoring System (PRAMS), 2004–2008. Centers for Disease Control and Prevention (CDC). MMWR Morb Mortal Wkly Rep 2012;61:25–9. [PubMed] [Full Text] ⇦
8. Landau SC, Tapias MP, McGhee BT. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. Contraception 2006;74:463–70. [PubMed] [Full Text] ⇦
9. Grossman D, Fernandez L, Hopkins K, Amastae J, Potter JE. Perceptions of the safety of oral contraceptives among a predominantly Latina population in Texas. Contraception 2010;81:254–60. [PubMed] [Full Text] ⇦
10. Landau S, Besinque K, Chung F, Dries-Daffner I, Maderas NM, McGhee BT, et al. Pharmacist interest in and attitudes toward direct pharmacy access to hormonal contraception in the United States. J Am Pharm Assoc (2003) 2009;49:43–50. [PubMed] ⇦
11. Abbott FV, Fraser MI. Use and abuse of over-the-counter analgesic agents. J Psychiatry Neurosci 1998;23:13–34. [PubMed] [Full Text] ⇦
12. Larson AM, Polson J, Fontana RJ, Davern TJ, Lalani E, Hynan LS, et al. Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study. Acute Liver Failure Study Group. Hepatology 2005;42:1364–72. [PubMed] [Full Text] ⇦
13. Food and Drug Administration. Combined hormonal contraceptives (CHCs) and the risk of cardiovascular disease endpoints. Silver Spring (MD): FDA; 2011. Available at: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM277384.pdf. Retrieved July 5, 2012. ⇦
14. Food and Drug Administration. FDA drug safety communication: updated information about the risk of blood clots in women taking birth control pills containing drospirenone. Silver Spring (MD): FDA; 2012. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm299305. Retrieved July 5, 2012. ⇦

15. Kaunitz AM. Clinical practice. Hormonal contraception in women of older reproductive age. N Engl J Med 2008; 358:1262–70. [PubMed] [Full Text] ⇦

16. Farley TM, Meirik O, Collins J. Cardiovascular disease and combined oral contraceptives: reviewing the evidence and balancing the risks. Hum Reprod Update 1999;5:721–35. [PubMed] [Full Text] ⇦

17. Grimes DA. Over-the-counter oral contraceptives—an immodest proposal? Am J Public Health 1993;83:1092–4. [PubMed] [Full Text] ⇦

18. Shotorbani S, Miller L, Blough DK, Gardner J. Agreement between women's and providers' assessment of hormonal contraceptive risk factors. Contraception 2006;73:501–6. [PubMed] [Full Text] ⇦

19. Grossman D, Fernandez L, Hopkins K, Amastae J, Garcia SG, Potter JE. Accuracy of self-screening for contraindications to combined oral contraceptive use. Obstet Gynecol 2008;112:572–8. [PubMed] [*Obstetrics & Gynecology*] ⇦

20. Doshi JS, French RS, Evans HE, Wilkinson CL. Feasibility of a self-completed history questionnaire in women requesting repeat combined hormonal contraception. J Fam Plann Reprod Health Care 2008;34:51–4. [PubMed] [Full Text] ⇦

21. Yeatman SE, Potter JE, Grossman DA. Over-the-counter access, changing WHO guidelines, and contraindicated oral contraceptive use in Mexico. Stud Fam Plann 2006;37: 197–204. [PubMed] ⇦

22. Kaskowitz AP, Carlson N, Nichols M, Edelman A, Jensen J. Online availability of hormonal contraceptives without a health care examination: effect of knowledge and health care screening. Contraception 2007;76:273–7. [PubMed] [Full Text] ⇦

23. Grossman D, White K, Hopkins K, Amastae J, Shedlin M, Potter JE. Contraindications to combined oral contraceptives among over-the-counter compared with prescription users. Obstet Gynecol 2011;117:558–65. [PubMed] [*Obstetrics & Gynecology*] ⇦

24. Gardner JS, Miller L, Downing DF, Le S, Blough D, Shotorbani S. Pharmacist prescribing of hormonal contraceptives: results of the Direct Access study. J Am Pharm Assoc (2003) 2008;48:212–26. [PubMed] ⇦

25. Potter JE, McKinnon S, Hopkins K, Amastae J, Shedlin MG, Powers DA, et al. Continuation of prescribed compared with over-the-counter oral contraceptives. Obstet Gynecol 2011;117:551–7. [PubMed] [*Obstetrics & Gynecology*] ⇦

26. White KO, Westhoff C. The effect of pack supply on oral contraceptive pill continuation: a randomized controlled trial. Obstet Gynecol 2011;118:615–22. [PubMed] [*Obstetrics & Gynecology*] ⇦

27. American College of Obstetricians and Gynecologists. Guidelines for women's health care: a resource manual. 3rd ed. Washington, DC: ACOG; 2007. ⇦

28. Stewart FH, Harper CC, Ellertson CE, Grimes DA, Sawaya GF, Trussell J. Clinical breast and pelvic examination requirements for hormonal contraception: Current practice vs evidence. JAMA 2001;285:2232–9. [PubMed] [Full Text] ⇦

29. Well-woman visit. Committee Opinion No. 534. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:421–4. [PubMed] [*Obstetrics & Gynecology*] ⇦

30. The importance of preconception care in the continuum of women's health care. ACOG Committee Opinion No. 313. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005;106:665–6. [PubMed] [*Obstetrics & Gynecology*] ⇦

31. Hopkins K, Grossman D, White K, Amastae J, Potter JE. Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users. Contraception 2012; DOI: 10.1016/j.contraception.2012.03.003. [PubMed] [Full Text] ⇦

32. Liang SY, Grossman D, Phillips KA. Women's out-of-pocket expenditures and dispensing patterns for oral contraceptive pills between 1996 and 2006. Contraception 2011;83:528–36. [PubMed] [Full Text] ⇦

33. Health Resources and Services Administration. Women's preventive services: required health plan coverage guidelines. Available at: http://www.hrsa.gov/womensguidelines. Retrieved August 10, 2012. ⇦

ISSN 1074-861X

Over-the-counter access to oral contraceptives. Committee Opinion No. 544. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012:120;1527-31.