Over-the-Counter Access to Hormonal Contraception

**ABSTRACT:** Barriers to access are one reason for inconsistent or nonuse of contraception. The requirement for a prescription can be an obstacle for some contraceptive users. Several studies have demonstrated that women are capable of using self-screening tools to determine their eligibility for hormonal contraceptive use. Pelvic and breast examinations, cervical cancer screening, and sexually transmitted infection screening are not required before initiating hormonal contraception and should not be used as reasons to deny access to hormonal contraception. Also, a plan to improve access to hormonal contraception should address cost issues. Pharmacist-provided contraception may be a necessary intermediate step to increase access to contraception, but over-the-counter access to hormonal contraception should be the ultimate goal. The American College of Obstetricians and Gynecologists supports over-the-counter access to hormonal contraception without age restrictions. This Committee Opinion has been updated to expand the focus of over-the-counter contraception to include oral contraceptive pills, vaginal rings, the contraceptive patch, and depot medroxyprogesterone acetate, to address the role of pharmacist-provided contraception, and to provide recommendations for individuals younger than 18 years.

**Recommendations and Conclusions**

Over-the-counter access to hormonal contraception (oral contraceptive pills [OCPs], the contraceptive patch, contraceptive vaginal rings, and depot medroxyprogesterone acetate [DMPA] injections) eliminates the need for prescriptions and relies on a woman to self-screen for eligibility. Based on the current evidence, the American College of Obstetricians and Gynecologists (ACOG) supports the following recommendations and conclusions:

- The American College of Obstetricians and Gynecologists supports over-the-counter access to hormonal contraception without age restrictions.
- Over-the-counter access has continuation rates of hormonal contraception comparable to prescription-only access and has the potential to decrease unintended pregnancy.
- Evidence demonstrates that women want over-the-counter access to hormonal contraception because it is easier to obtain.
- Data support that progestin-only hormonal methods are generally safe and carry no or minimal risk of venous thromboembolism (VTE).
- The VTE risk with combined oral contraceptive use is small compared with the increased risk of VTE during pregnancy and the postpartum period.
- Pelvic and breast examinations, cervical cancer screening, and sexually transmitted infection screening are not required before initiating hormonal contraception and should not be used as reasons to deny access to hormonal contraception.
- Several studies have demonstrated that women are capable of using self-screening tools to determine their eligibility for hormonal contraceptive use.
- The goal of over-the-counter access is to improve availability of hormonal contraception, but not at the expense of affordability. Also, a plan to improve access to hormonal contraception should address cost issues.
- Pharmacist-provided contraception may be a necessary intermediate step to increase access to contraception, but over-the-counter access to hormonal contraception should be the ultimate goal.

**Background**

This Committee Opinion has been updated to expand the focus of over-the-counter contraception to include
oral contraceptive pills, vaginal rings, the contraceptive patch, and depot medroxyprogesterone acetate, to address the role of pharmacist-provided contraception, and to provide recommendations for individuals younger than 18 years. This Committee Opinion does not address emergency contraception. For information on emergency contraception, see ACOG Practice Bulletin No. 152, *Emergency Contraception* and ACOG Committee Opinion No. 707, *Access to Emergency Contraception* (1, 2).

Barriers to access are one reason for inconsistent or nonuse of contraception. The requirement for a prescription can be an obstacle for some contraceptive users (3–6). One national survey of 1,385 women reported that among the 68% of individuals who had ever tried to obtain a prescription for hormonal contraception, 29% had problems accessing the initial prescription or refills. Reported obstacles included the following: cost barriers or lack of insurance (14%); challenges in obtaining an appointment or getting to a clinic (13%); the health care provider requiring a clinic visit, examination, or Pap test (13%); not having a regular physician or clinic (10%); difficulty accessing a pharmacy (4%); and other reasons (4%) (6).

Some states have increased the ways in which women can obtain prescriptions for contraception and the ways in which contraception is dispensed. As of April 2019, pharmacists in 13 states and the District of Columbia legally can prescribe or directly dispense some types of hormonal contraception (7). This access is termed “pharmacy access” or “behind-the-counter access.” In this situation, a woman consults with a pharmacist before receiving the prescription. The consultation generally consists of completing a questionnaire to identify contraindications and a having blood pressure measurement (8). Potential barriers related to behind-the-counter access include age restrictions in some states, individual pharmacists’ conscientious objections to contraception provision, and health insurance plans that do not cover the cost of the pharmacist consultation. A national survey of 2,725 pharmacists reported that 85% were interested in providing hormonal contraception services, although some cited potential obstacles including lack of time, reimbursement issues, and possible resistance from physicians (9). Additionally, online access, which is permitted in some areas in the United States, allows a woman to bypass the office visit and obtain a prescription for some types of hormonal contraception by answering a series of online questions or by talking to a clinician through telemedicine (eg, video or online call) (10). The contraceptives then are delivered to the individual’s home. Although pharmacy access and online access may eliminate some barriers, full over-the-counter access to hormonal contraception could provide a more comprehensive solution to contraceptive access and is a reasonable goal from a larger public health viewpoint.

**Interest in Over-the-Counter Access**

Surveys repeatedly have demonstrated interest among adolescents and adult women in over-the-counter access to oral contraceptives (3, 11, 12). A 2011 national survey about views on over-the-counter oral contraceptives queried 2,046 women aged 18–44 years who are sexually active with a male partner and who reported they do not desire pregnancy. Two thirds (62%) were “strongly” or “somewhat” in favor of over-the-counter access, and 37% reported that they were likely to use this option. Those who might use this option reported being willing to pay a maximum of $20 per month (13). Another nationally representative, cross-sectional online survey of approximately 2,500 females (aged 15–44 years) reported that 39% of adult women aged 18–44 years and 29% of adolescents (aged 15–17 years) would probably use progestin-only pills if they were available over-the-counter. Women aged 18–44 years were willing to pay $15 per month and adolescents (aged 15–17 years) $10 per month, on average (14). Additionally, focus group data from adolescent females and adult women have shown support for over-the-counter access (15, 16).

Some health care providers and pharmacists have voiced support for over-the-counter access to hormonal contraception. A web-based survey of 617 physicians, nurse practitioners, certified nurse-midwives, physician assistants, and registered nurses (recruited from the National American Society for Pediatric and Adolescent Gynecology, National Family Planning and Reproductive Health Association, American Society of Adolescent Health and Medicine, and the Association of Reproductive Health Professionals) reported that 28% supported over-the-counter access to OCPs, the contraceptive patch, and the monthly contraceptive vaginal ring, and 17% supported over-the-counter access to DMPA (17). Health care providers cited the following concerns about over-the-counter provision of contraception: a potential decrease in preventive screenings, changes to the patient–provider relationship, including loss of patients, and loss of revenue (17). The Women’s Health Practice and Research Network of the American College of Clinical Pharmacy supports changing oral contraceptives to over-the-counter status with two caveats: 1) pills would be sold where a pharmacist is on duty and 2) mechanisms would exist to cover over-the-counter contraceptives through Medicaid to decrease out-of-pocket costs to individuals (18). In addition to ACOG, the American Academy of Family Physicians, the American Medical Association, and the American Public Health Association support over-the-counter access to contraception (8).

**Data on Adherence and Continuation**

Over-the-counter access appears to have similar rates of adherence and continuation when compared with
prescription-only access. One third of women who start using an oral contraceptive will have stopped using the method by the end of the first year (19). Reasons for discontinuation include adverse effects and difficulty with a daily method as well as access issues, including cost and lack of time for a medical visit to obtain a prescription (5, 6). Notably, reasons for discontinuation of contraception are complex and include the desire for pregnancy, although reduction of barriers to access is important for those individuals who wish to continue their preferred method of contraception. A study of nearly 1,000 OCP users (half of whom obtained their pills from an over-the-counter pharmacy in Mexico and half of whom obtained pills by prescription from a family planning clinic in El Paso, Texas) reported that at 9 months, 79.2% of the over-the-counter group and 74.9% of the prescription group had continued their pill use \((P=.12)\) (20). Additionally, when adjusting for differences (age, country of birth, country where education was completed, U.S. health insurance status, receipt of government assistance, border-crossing frequency, duration of use of OCPs, experience of adverse effects attributable to OCPs, and how long the woman reported she planned to use OCPs), a higher rate of discontinuation for women who obtained pills in El Paso clinics (25.1%) compared with those who obtained their pills without a prescription in Mexico was reported (20.8%; hazard ratio, 1.6; 95% CI, 1.1–2.3).

Access to multiple OCP packs at one time (which may be understood as a proxy for increased access) results in higher rates of continuation. In a 2011 randomized trial, investigators compared 6-month contraceptive continuation rates among women who were dispensed a 3-month supply of pills and those who received a 7-month supply of pills (21). Participants who received seven pill packs had a higher 6-month continuation rate than participants who received three pill packs and were required to return for further refills (51% compared with 35%; \(P<.001\)), and the effect was greater among participants younger than 18 years (49% compared with 12%; \(P<.001\)) (21). These findings are reassuring and support the view that adolescents and women who obtain their contraception over-the-counter are as likely to adhere to a regimen and to continue the method as those who obtain contraception by prescription.

The 1-year continuation rate for DMPA injection is approximately 56% (19). The requirement to return to a clinic every 3 months for an injection can lead to missed appointments and undesired discontinuation (22). Several studies have demonstrated interest in and the feasibility and continuous use of self-administered subcutaneous DMPA, although it is not currently labeled in the U.S. for self-administration (23–26). Self-administration would make DMPA an option for over-the-counter access. A 2014 randomized controlled trial of women presenting to a New York City family planning clinic to initiate, restart, or continue DMPA found that when comparing self-administration of subcutaneous DMPA with health care provider administration, 71% of the self-administration group versus 63% of the health care provider administration group continued using DMPA at 1 year (27). A 2018 study of 401 females aged 15–44 years requesting DMPA at clinics in Texas and New Jersey randomized participants to self-administration or clinic-administration of subcutaneous DMPA and reported that 1-year continuous use of DMPA was 69% in the self-administration group and 54% in the clinic group \((P=.005)\) (25). Similarly, a study in Malawi found that continuation rates were higher in the 364 women randomly assigned to self-administer subcutaneous DMPA compared with the 367 women assigned to the health care provider-administered group (73% versus 45%; RR, 0.40; 95% CI, 0.31–0.51) (24).

**Switch From Prescription to Over-the-Counter Status**

Drug manufacturers can submit a new drug application to the U.S. Food and Drug Administration (FDA) to make a switch from prescription to over-the-counter access for a medication. The U.S. Food and Drug Administration review for a switch includes three stages: 1) a consumer evaluation of labeling, 2) a self-selection study to determine if consumers can accurately self-screen, and 3) an actual-use study (Fig. 1). The key factors when the FDA considers a change from prescription to over-the-counter status are the potential toxicity of the medication and whether the medication can benefit consumers without endangering their safety. Labels and package inserts for over-the-counter drugs must be written so that key information is understandable by the layperson, including individuals with low reading comprehension skills, and so that individuals can use this information to determine whether the product is appropriate for them without the help of a health care provider. The U.S. Food and Drug Administration requires that the package insert outlines the drug’s benefits and risks and includes therapeutic indications, instructions for self-screening for contraindications, dosage instructions, and warnings about adverse effects and preventing misuse (8). Currently, efforts are underway to perform actual-use studies for progestin-only pills to determine whether individuals can select and use the method appropriately in an over-the-counter setting (28).

**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 and ibuprofen, have documented adverse effects, including gastrointestinal bleeding (29). These effects may occur even at low doses used for prophylaxis of cardiovascular disease.
Additionally, over-the-counter use of acetaminophen is linked to serious liver damage (30).

Safety concerns about hormonal contraception frequently focus on the risk of VTE, a rare event in women of reproductive age, although its incidence increases with age and pregnancy (Fig. 2) (31). The rate of VTE among healthy nonpregnant women of reproductive age is one-to-five events per 10,000 woman-years (Fig. 2) (32). Data support that progestin-only hormonal methods are generally safe and carry no or minimal risk of VTE. A systematic review concluded that there was no statistically significant increased risk of VTE among women in the general population using progestin-only pills, implants, or levonorgestrel intrauterine devices, compared with nonusers (33). Limited evidence suggested that the use of DMPA was associated with a slightly elevated risk of VTE. This systematic review also concluded that among women with comorbid medical conditions that may increase baseline risk of VTE, the use of progestin-only contraceptives did not further elevate the risk (33). Any increased VTE risk that progestin-only methods carry likely would translate into a small increase in absolute numbers of thrombotic events at the population level (33).

Combined hormonal methods contain estrogen (most commonly ethinyl estradiol) in combination with different progestins. Ethinyl estradiol increases the production of liver proteins involved in the coagulation process, resulting in slight procoagulant effects, and these changes are thought to relate to the increased risk of VTE, approximately three-to-nine events per 10,000 woman-years of exposure for combined OCP users (33, 34). The evidence examining the association of VTE risk with nonoral hormonal contraceptive use (the contraceptive patch and monthly vaginal ring) is inconsistent. It is unclear whether patch or ring users have a higher risk of VTE compared with women who use combined oral contraceptives; however, any potential increased risk in VTE likely represents a small number of events on a population level (35). The VTE risk with combined oral contraceptive use is small compared with the increased risk of VTE during pregnancy (5–20 per 10,000 woman-years) and the postpartum period (up to 12 weeks) (40–65 per 10,000 women-years) (Fig. 2). The risk of other cardiovascular events, such as stroke and acute myocardial infarction, is low in healthy, reproductive-aged women, and there is conflicting evidence whether use of combined hormonal contraception increases that risk (36–39).

Although obesity and use of combined hormonal contraception represent independent risk factors for VTE, the absolute risk of VTE with combined hormonal contraception in women with obesity remains less than the risk of VTE during pregnancy and the puerperium (40). Obesity also is a risk factor for acute myocardial infarction and stroke; however, the data on whether this risk is higher for women with increasing body mass index who use combined hormonal methods in comparison to normal-weight combined oral contraceptive users are inconsistent (37). Overall, obesity should not be a reason to withhold hormonal contraception (40).

For DMPA to be available over-the-counter, women will need to self-administer subcutaneous injections safely. Presently, individuals with diabetes and women undergoing fertility treatments successfully self-inject subcutaneous insulin and follicle-stimulating hormone, respectively, safely at home, most often using a pre-filled injection pen. Although not commercially available in the United States, a subcutaneous DMPA pre-filled injection system has been developed and was studied in 120 women in Belgium (41). Participants were randomly assigned either to a group that received hands-on training on how to administer subcutaneous DMPA injections using a pre-fillable injection system in a simulation setting or to a group that did not receive training (41). Investigators found high rates of successful
administration of the injection in both groups, with success higher on day 1 and at month 3 in the group that received training compared with the untrained group (90% and 96.7% versus 76.7% and 88.3%, respectively). No safety issues were identified in the study (41). A second small study (N=30) concluded that self-injection of DMPA was feasible and safe and recommended a plan to train women before they attempt self-injection (23).

Self-Screening

An important consideration related to over-the-counter hormonal contraception availability and self-screening is the actual prevalence of medical contraindications to hormonal contraceptives among women in the United States. A Contraceptive CHOICE Project secondary data analysis found that of 1,010 adolescents and adult women who desired a combined hormonal contraceptive method, 70 women (6.9%) self-reported having a potential medical contraindication on their baseline questionnaire (42). The Contraceptive CHOICE Project included females aged 14–45 years. Those who chose combined hormonal contraception at baseline were younger (mean age of 23.7 years) than those who chose long-acting reversible contraceptive methods (mean age of 25.7 years). Research charts of women with self-reported medical contraindications were reviewed to verify all conditions. After chart review, only 24 of 1,010 participants (2.4%) who desired a combined hormonal method were confirmed to have a true medical contraindication. In this study, the comorbid medical conditions identified were hypertension, migraines with aura, history of VTE, and smoking at age 35 years or older. A study of progestin-only pills (a method with even fewer contraindications than combined hormonal contraception) reported that among a sample of 1,267 reproductive-aged women in the general population, only 1.6% had contraindications to the progestin-only pills (43). The most common contraindication was the use of certain medications for tuberculosis or seizures (0.9%); however, although these medications reduce the effectiveness of progestin-only pills, the interaction otherwise does not harm users.

Despite the safety of its use, hormonal contraception is not appropriate for every patient. Over-the-counter availability of hormonal contraception would require that females of all ages self-screen for contraindications. In one study that compared current family planning clients’ self-assessment of contraindications with clinical assessment, 392 of the 399 participants (females aged 15–45 years) and health care provider pairs obtained agreement on medical eligibility criteria (greater than 95%) (44). Similar findings were seen among women in the general population, although in one study approximately 6% of the 1,271 women aged 18–49 years had unrecognized hypertension (45). 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 finding that women take a more conservative approach compared with health care providers and also demonstrated that none of the 328 women studied would have incorrectly used OCPs based on self-screening (46). Another study of women living in Mexico found that women obtaining OCPs from pharmacies were no more likely to have contraindications than those who received OCPs from a clinic (47). An Oregon-based study of women seeking to buy OCPs online through a special program found that online participants (n=243) were as knowledgeable about contraindications and adverse events as women seen in the clinic (n=161) (48). However, the study authors 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 combined OCPs over-the-counter in Mexican pharmacies were more likely to have relative contraindications but not absolute contraindications when compared with women who obtained combined OCPs in U.S. public clinics (49). At least one relative contraindication (e.g., adequately controlled hypertension, being fewer than 21 days postpartum and not breastfeeding, breastfeeding 6 weeks or fewer to more than 6 months postpartum, migraine headaches without aura) to combined OCP use was found in 13% of the over-the-counter group versus 9% of the prescribed group (P=.006). Similar frequencies of absolute contraindications were found in the two
groups (7% versus 5%; P=.162). However, women who purchased combined OCPs over-the-counter in this study did not self-screen using a standardized process and the circumstances of patients (eg, lacking access to primary care) may have affected the outcome.

Pharmacist screening for behind-the-counter access to hormonal contraceptive methods also has been evaluated. In the Direct Access Study, several pharmacists received specialized education in the provision of hormonal contraceptive methods and were authorized to provide hormonal contraception, including OCPs, the transdermal patch, and the monthly vaginal ring (50). Pharmacists successfully used checklists to identify women without contraindications to hormonal contraceptives according to the World Health Organization’s Medical Eligibility Criteria for Contraceptive Use. Blood pressure and body mass index also were measured.

Although the prevalence of contraindications to hormonal contraception is low in reproductive-aged women, an effective screening tool for over-the-counter contraception is important. See Box 1 for important information that should be considered for manufacturer-developed screening checklists. The Centers for Disease Control and Prevention’s 2016 U.S. Selected Practice Recommendations for Contraceptive Use provides recommendations for tests or examinations needed before starting specific contraceptive methods (51). Depot medroxyprogesterone acetate and progestin-only pills do not require any tests or examinations before initiation. The U.S. Selected Practice Recommendations for Contraceptive Use advises that before starting combined hormonal contraceptives (combined oral contraceptives, transdermal patch, and the monthly vaginal ring), blood pressure should be measured. A blood pressure measurement from a recent health care provider visit could be used. Alternatively, patients could measure their blood pressure using a pharmacy-based or home-based monitor. Baseline weight and body mass index measurements may be useful for women initiating hormonal contraceptive methods in general but are not required because obesity alone is not a contraindication to any type of hormonal contraceptive method.

Use of Preventive Services

Another theoretical concern is that women who access over-the-counter hormonal contraception will forgo screening and other preventive services. However, pelvic and breast examinations, cervical cancer screening, and sexually transmitted infection screening are not required before initiating hormonal contraception and should not be used as reasons to deny access to hormonal contraception (51–54).

In a 2012 study, researchers compared the screening habits of U.S. women who had obtained their oral contraceptives from U.S. clinics with those who had obtained them directly from Mexican pharmacies (55). Both groups reported high rates of Pap tests within the past 3 years (greater than 88%), ever having received sexually transmitted infection 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 women receiving oral contraceptives from clinics. Among women receiving over-the-counter oral contraceptives, the reasons given for not having a Pap test included inconvenience, cost, and not knowing where to obtain the test.

Access and Affordability

The goal of over-the-counter access is to improve availability of hormonal contraception, but not at the expense of affordability. It is possible that some women might be affected adversely by changing hormonal contraception from prescription to over-the-counter access if they lose insurance coverage for their preferred method. To cover the cost of over-the-counter medications, some insurers might require a prescription, which would then defeat the purpose of moving the medication away from prescription status. Nevertheless, the current Patient Protection and Affordable Care Act’s contraception mandate includes, for example, the coverage of female condoms and spermicides with no out-of-pocket cost, so a model for insurance coverage of

<table>
<thead>
<tr>
<th>Box 1. Example of Patient Checklist for Over-the-Counter Combined Hormonal Contraception</th>
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<tbody>
<tr>
<td>1. Are you a smoker age 35 or older?</td>
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<tr>
<td>2. Do you think you might be pregnant?</td>
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<tr>
<td>3. Have you had a baby in the past 3 weeks?</td>
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<td>4. Are you currently breastfeeding and your baby is less than 6 months old?</td>
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<td>5. Do you have high blood pressure?</td>
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<td>6. Have you had a heart attack or stroke?</td>
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<td>7. Do you have heart disease?</td>
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<tr>
<td>8. Have you had a blood clot (thrombosis) in your lung or in your leg (NOT just varicose veins)?</td>
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<tr>
<td>9. Do you have diabetes?</td>
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<tr>
<td>10. Do you have migraine headaches?</td>
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<tr>
<td>11. Do you have liver disease or have you had liver cancer?</td>
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<tr>
<td>12. Do you have gall bladder disease?</td>
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<tr>
<td>13. Have you had breast cancer?</td>
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<tr>
<td>14. Do you take medicine for high cholesterol?</td>
</tr>
<tr>
<td>15. Do you take medicine for seizures or tuberculosis?</td>
</tr>
</tbody>
</table>

over-the-counter contraceptives exists. A plan to improve access to hormonal contraception should address cost issues.

Age Restrictions
The American College of Obstetricians and Gynecologists supports over-the-counter access to hormonal contraception without age restrictions. However, hormonal contraception should not be initiated before menarche. Historically, age has been a barrier to hormonal contraception. Adolescents may not be able to travel to a health care setting on their own or may not be able to afford the fee to see a clinician to discuss contraception. Another important issue related to adolescent access to reproductive health care is confidentiality (56). Adolescents covered under their parents’ health insurance may find their confidentiality breached by Explanation of Benefits statements from the insurer sent to their home. As it does for adults, over-the-counter access to hormonal contraception has the potential to reduce barriers and increase hormonal contraceptive use for adolescents (57). Although rare, age-based restrictions on over-the-counter medications do exist. Currently, only the sale of nicotine replacement products is restricted to those 18 and older. In 2015, the Oral Contraceptives Over-the-Counter Working Group convened adolescent health care experts to review the scientific and regulatory issues related to a possible over-the-counter switch for OCPs. These experts concluded that OCPs are safe and effective for adolescent users and there is no scientific rationale for limiting access to a future over-the-counter OCP product by age (57). Nevertheless, the FDA may expect label comprehension and self-screening studies in adolescents to determine whether an age restriction will be placed on over-the-counter access to contraception.

Conclusion
The American College of Obstetricians and Gynecologists supports improving access to hormonal contraception. Pharmacist-provided contraception may be a necessary intermediate step to increase access to contraception, but over-the-counter access to hormonal contraception should be the ultimate goal. Evidence demonstrates that women want over-the-counter access to hormonal contraception because it is easier to obtain. Over-the-counter access has continuation rates of hormonal contraception comparable to prescription-only access and has the potential to decrease unintended pregnancy. Although progestin-only methods have few contraindications and are safe for almost all women, combination methods containing estrogen do carry an increased risk of VTE and, thus, an adequate self-screening tool is necessary. Several studies have demonstrated that women are capable of using self-screening tools to determine their eligibility for hormonal contraceptive use. Age should not be a barrier for access to hormonal contraception, and ACOG supports over-the-counter access for adolescents. A plan to improve access to hormonal contraception should address cost issues.

References
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42. Xu H, Eisenberg DL, Madden T, Secura GM, Peipert JF. Medical contraindications in women seeking combined


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