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Original article

## Women's Perspectives on Age Restrictions for Over-the-Counter Access to Oral Contraceptives

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 A B S T R A C T

**Purpose:** There is a growing movement for an over-the-counter (OTC) oral contraceptive (OC) in the United States. This study aimed to explore women's views regarding an age restriction for an OTC OC.

**Methods:** From November to December 2011, we administered a nationally representative survey of U.S. women aged 18–44 years who were at risk of unintended pregnancy to explore their opinions of an age restriction for an OTC OC. A total of 2,046 women completed the survey. Weighted proportions were calculated, and logistic regression was used to identify covariates associated with supporting an age restriction. Chi-square tests of potential advantages and disadvantages of OTC access to OCs by support for an age restriction were also performed.

**Results:** Overall, 26% of respondents supported an age restriction for an OTC OC; 28% were against an age restriction, and 46% were unsure. In multivariable analysis controlling for overall support for OTC access to OCs and for other covariates, women were more likely to support an age restriction for an OTC OC if they had less than a high school degree (odds ratio [OR], 2.5), a high school degree (OR, 1.6), or some college (OR, 1.6) compared with a college degree; if they were married compared with never married (OR, 2.1); and if they lived in the Midwest (OR, 2.1) or South (OR, 2.1) compared with the West.

**Conclusions:** A minority of women support an age restriction. Women's concerns about a potential OTC OC should be addressed through education and ongoing research.

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 IMPLICATIONS AND CONTRIBUTION

Momentum is growing for an over-the-counter (OTC) oral contraceptive in the United States. Given the history of OTC emergency contraception, it is likely that an age restriction will be a focus of debate. It is therefore important to include adolescents in necessary research for an OTC switch.

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Oral contraceptives (OCs) are the most popular form of birth control in the United States [1], and research indicates that they meet the criteria of the U.S. Food and Drug Administration (FDA) for over-the-counter (OTC) status [2,3]. Research among adult women shows that they are able to accurately use simple checklists to determine whether they have a contraindication to using OCs—a condition that might make the pill dangerous or less effective [4–6]—and that U.S. women are interested in using nonprescription pill access, including women using no method or a less-effective method such as condoms only [7,8]. This,

combined with studies demonstrating improved pill continuation among OTC users compared to clinic users [9], indicates that OTC access may help women to prevent unintended pregnancy. In light of this, in December 2012, the American College of Obstetricians and Gynecologists issued a Committee Opinion in support of moving OCs OTC [10].

If an OTC switch for an OC product moves forward, it is likely that an age restriction will be a focus of debate. Although emergency contraception (EC) is safe for both adolescent and adult use, it took a decade for Plan B EC to become available OTC for women of all ages in the United States. The process was at times politically fraught but also encountered stumbling blocks because of an initial limited amount of actual-use data among adolescents under the age of 16 years [11,12]. The history of EC underscores the importance of addressing issues related to an age restriction for an OTC OC pill from the beginning.

Evidence so far does not indicate a compelling reason to exclude minors from the population that should be able to access a future OTC OC. The prevalence of contraindications to combined OC pills is significantly lower among younger compared with older women [5] and is low among women of all ages for a progestin-only OC pill [6]. Additionally, adolescents face unique age-related barriers to contraception access, including concerns related to disclosure of confidential information and their ability to access services without the consent of a parent or guardian [13], which could be ameliorated with OTC access to the pill. Although there is limited research with teens on their opinions of OTC OC access, a 2011 survey conducted among women seeking abortion at six U.S. clinics found high interest. Nearly half of respondents (47%) aged 15–17 years and 62% aged 18–19 years reported being likely to use an OTC OC if it was available [8].

Research has not yet explored whether teens can understand an OTC label for an OC product or whether they would use the product safely and effectively. However, for the previously mentioned reasons, adolescents should be included in this necessary research to support a prescription-to-OTC switch application to the FDA. Additionally, there has not been any research on public opinion related to an age restriction for an OTC pill. Although public opinion is not a formal consideration for FDA approval of an OTC OC product, it could influence a pharmaceutical company's decision making around whether to apply for dual label or true OTC status. The objective of this study was to understand the opinions on an age restriction among U.S. adult women who might use a future OTC OC.

## Methods

From November to December 2011, we administered a nationally representative survey of adult U.S. women who were at risk of unintended pregnancy to explore their opinions of an age restriction for OTC access to OCs. These data were collected as part of a larger survey that included questions about women's support for and likelihood of using OTC access to OCs in the United States [7]. Women aged 18–44 years, living in the United States, who spoke English or Spanish, and who were considered at risk for unintended pregnancy (i.e., they had had heterosexual intercourse in the past 12 months, were not pregnant or trying to get pregnant, had not delivered a baby in the past 2 months, and were not protected by male or female sterilization [14]) were eligible to participate. The survey was conducted in English or Spanish with women in all 50 states and the District of Columbia and was administered by Knowledge Networks using

their KnowledgePanel, a nationally representative, probability-based, nonvolunteer, online household panel [15]. The panel methodology and details for this survey have been previously described [7].

The target sample size for the survey was 2,000. The maximum margin of error in the estimation of proportions at a 95% confidence level for a sample of 2,000 with a design effect of 1.8 (i.e., the ratio of actual variance due to weighting to the variance that would be computed under the assumption of simple random sampling with no poststratification weighting) was estimated to be  $\pm 2.9\%$ .

Participants were asked a series of screening questions, and eligible participants gave informed consent before completing the survey. The study was approved by the Allendale Investigational Review Board.

Knowledge Networks provided a data file with weighting variables that incorporated design-based weights accounting for panel recruitment and study-specific poststratification weights benchmarked against the demographic and geographic distributions for noninstitutionalized women aged 18–44 years from the most recent Current Population Survey [16]. The weights were also benchmarked against the Spanish language distributions from the most currently available Pew Hispanic Center Survey [17].

The survey included questions about participants' background characteristics, contraceptive use, and support for and interest in using OCs obtained without a prescription. OTC access was described to participants as "birth control pills would be available on a shelf at a drug store or grocery store just like cough medicine or some allergy pills. If you had a question, you could talk to a pharmacist. You would not need a prescription from a doctor or nurse. If you have insurance, your insurance may or may not cover 'over-the-counter' birth control pills."

Participants were asked whether they supported OTC access to OCs with the following question: "What is your opinion of birth control pills being available over the counter in pharmacies or grocery stores? Even if you are not interested in using over-the-counter pills yourself, are you in favor of over-the-counter birth control pills being available for other women? It's important to remember that even if pills were available over the counter, a woman could still talk to a pharmacist if she had questions about the pills, or she could go to a clinic to talk to a doctor or nurse if she wanted to." Additionally, participants were given a list of potential advantages and disadvantages of OTC access to OCs and were asked to mark the ones with which they agreed.

To assess whether participants supported an age restriction for OTC access to OCs, participants were asked the following question: "As you may know, when emergency contraception (also known as "the morning-after pill" or "Plan B") initially became available over the counter, there was an age limit: women under age 18 needed a prescription—even though studies showed that teenagers were able to safely use the medication and did not engage in riskier sex when they had access to it. If research showed that teenagers were able to safely use an over-the-counter daily birth control pill, would you support their being able to buy it without a prescription?" Women were considered to support an age restriction for OTC access if they responded "no" (vs. "yes," "maybe—it depends on other factors, like what the studies show or what the lower age limit is," or "not sure").

Data analysis was conducted using the survey function within Stata 12.0 (Stata, StataCorp, College Station, TX) to account for

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