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A Survey of Teenagers’ Attitudes Toward Moving Oral Contraceptives Over the Counter

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A Survey of Teenagers’ Attitudes Toward Moving Oral Contraceptives Over the Counter

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An abstract of
A thesis submitted to the faculty of the
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Abstract

A Survey of Teenagers’ Attitudes Toward Moving Oral Contraceptives Over the Counter

By Ruth Manski

Introduction: Evidence suggests that over-the-counter access to oral contraceptives may improve contraceptive access and use among adult women. Teenagers may particularly benefit from over-the-counter access, as they experience disproportionately high rates of unintended pregnancy and face unique challenges accessing contraception. However, limited research has explored teenagers’ attitudes toward over-the-counter access.

Methodology: During September 2014, 348 females aged 14-17 were recruited via Facebook advertisements to participate in an online survey to assess teenagers’ attitudes toward over-the-counter access and understanding of how to use oral contraceptives based on reading a prototype over-the-counter product label. Descriptive statistics and bivariate analyses were conducted using SPSS; Pearson chi-square and Fisher’s exact tests were conducted for categorical outcomes and independent t-tests and one-way ANOVA for continuous outcomes.

Results: Seventy-three percent of participants reported being in favor of over-the-counter access and 61% reported that they would be likely to use oral contraceptives through over-the-counter access. Participants who had sex were significantly more likely to be interested in using over-the-counter access (77%) compared to participants who had not had sex (48%). Participants understood an average of 7.1 of 8 key concepts that the prototype over-the-counter product label was intended to convey; no significant differences were found among subgroups.
**Discussion:** Participants in this sample are interested in using oral contraceptives over the counter and can understand how to use an over-the-counter product. These findings, in combination with evidence documenting the safety and effectiveness of over-the-counter access, support continued exploration of reclassification of oral contraceptives to over-the-counter status without age restriction.
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Chapter 1: Introduction

Introduction and Rationale

Unintended pregnancy among teenagers in the United States is an important public health issue, as 82% of pregnancies in women 15-19 are unintended (Finer & Zolna, 2011). Unintended pregnancies are associated with a range of negative health outcomes, including low birth weight babies, late or no prenatal care, and smoking and drinking during pregnancy, which are disproportionately experienced by teenagers (Cheng, Schwarz, Douglas, & Horon, 2009; Gipson, Koenig, & Hindin, 2008; Kost & Lindberg, 2015). Teen mothers are more likely to receive inadequate prenatal care and have low birth weight babies compared to older mothers (Guttmacher Institute, 2014).

Among the over 3.3 million unintended pregnancies each year, the majority result from inconsistent use or nonuse of contraception (Guttmacher Institute, 2015b). Lack of access to contraception has been reported as a main reason for contraceptive nonuse among teenagers experiencing an unintended pregnancy (Centers for Disease Control and Prevention, 2012). Challenges accessing contraception, including cost, lack of transportation or health insurance, inaccessible healthcare provider and pharmacy locations, and confidentiality concerns can lead to gaps in teenagers’ contraceptive use and increase their risk of unintended pregnancy (Brindis & Davis, 1998; Hock-Long, Herceg-Baron, Cassidy, & Whittaker, 2003; Oberg, Hogan, Bertrand, & Juve, 2002). Strategies to increase teenagers’ access to and use of contraception are needed.

Problem Statement

A growing body of evidence suggests that removing the prescription requirement for oral contraceptive pills (OCPs) – or what is commonly referred to as over-the-counter (OTC) access
to OCPs – may improve contraceptive access and use among adult women (American College of Obstetricians and Gynecologists, 2012; Dennis & Grossman, 2012; Grindlay, Foster, & Grossman, 2014; Grossman & Fuentes, 2013; Grossman et al., 2013; Potter et al., 2011). OTC access to OCPs would mean that women could buy OCPs on a shelf at a drugstore or grocery store and would not need a prescription from a healthcare provider. Research suggests that women can accurately screen themselves for medical contraindications to OCPs, conditions that would make using OCPs unsafe or less effective (Grossman et al., 2008; Shotorbani, Miller, Blough, & Gardner, 2006); that they support OTC access and are interested in using an OTC product (Dennis & Grossman, 2012; Grindlay et al., 2014; Grossman et al., 2013); and that OTC access may increase OCP continuation (Potter et al., 2011). Several medical organizations, including the American Congress of Obstetricians and Gynecologists, have issued statements in support of removing the prescription requirement, citing the safety and effectiveness of OTC access (American Academy of Family Physicians, 2014; American College of Obstetricians and Gynecologists, 2012; American Medical Association, 2013; McIntosh et al., 2011).

Teenagers may particularly benefit from OTC access, as they experience disproportionately high rates of unintended pregnancy and face unique age-related challenges accessing contraception (Finer, 2010; Finer & Zolna, 2011). However, limited research has explored teenagers’ interest in OTC access or attitudes toward OCPs being available through this provision model. Studies with adult women suggest that women have concerns about teenagers’ access to OTC OCPs, including their abilities to correctly use OCPs without counseling from a healthcare provider (Dennis & Grossman, 2012; Grossman et al., 2013); the relevancy of these concerns has not yet been explored.
Purpose Statement

The aims of this research study are:

1. To explore female teenagers’ attitudes toward OCPs being available for teenagers through OTC access, including:
   a. Teenagers’ level of support for OTC access to OCPs;
   b. Teenagers’ interest in using OCPs through OTC access;
   c. Teenagers’ perceptions of the advantages and disadvantages of OTC access; and
   d. Teenagers’ willingness and ability to pay for OCPs through OTC access; and

2. To assess female teenagers’ understanding of how to use OCPs based on reading a prototype over-the-counter product label.

Significance Statement

This study will address significant gaps in the existing scholarship on OTC access to OCPs and will help inform future policy decisions to move OCPs OTC for teenagers. The recent debate around removing the prescription requirement for Plan B emergency contraception (EC) without age restriction suggests that any decision to move OCPs OTC will face similar challenges surrounding teenagers’ access to an OTC product (US Food and Drug Administration, 2013). Research documenting teenagers’ attitudes toward OTC access and understanding of how to use OCPs based on reading a prototype over-the-counter product label will provide critical information about the benefits and drawbacks of teenagers’ access to OTC OCPs. Study findings will be valuable to advocates working to move OCPs OTC and pharmaceutical companies as they decide whether to include teenagers in research about the acceptability of OTC OCPs.
Additionally, given that teenagers experience unique age-related contraceptive barriers, such as challenges accessing contraceptive services without parental consent and concerns about parental disclosure of confidential information, removal of the prescription requirement for OCPs may particularly benefit this population (Finer, 2010; Finer & Zolna, 2011).
Definition of Terms

Adolescents – Refers to individuals between the ages of 10 and 19 (World Health Organization, 2015).

Birth control pills – Refers to combined oral contraceptives (COCs) and progestin only pills (POPs). Used interchangeably with the term “oral contraceptive pills.”

Combined oral contraceptives (COCs) – Oral contraceptive pills that contain the hormones estrogen and progestin.

Oral contraceptive pills (OCPs) – Refers to combined oral contraceptives (COCs) and progestin only pills (POPs). Used interchangeably with the term “birth control pills.”

Over-the-counter (OTC) access – Obtaining birth control pills from a shelf at a drugstore or grocery store, similar to how one would obtain shampoo or vitamins. Women would not need a prescription from a healthcare provider and would not need to talk to anyone about buying birth control pills unless they wanted to. Health insurance may or may not cover the cost of birth control pills bought OTC.

Pharmacy access – Obtaining birth control pills from a pharmacist at a drugstore or grocery store. Women would not need a prescription from a healthcare provider, but they would need to ask the pharmacist for birth control pills and answer some questions about their health before getting the pills. Health insurance may or may not cover the cost of birth control pills bought through pharmacy access.

Progestin only pills (POPs) – Oral contraceptive pills that contain the hormone progestin and do not contain estrogen. Also referred to as “mini-pills.”
Teenager/teen – Refers to individuals aged 13-19. The term teenager/teen, rather than adolescent, was used throughout the survey instrument to refer to someone the same age as the study participant (age 14-17).
Chapter 2: Comprehensive Review of the Literature

This chapter will review the literature regarding unintended pregnancy and contraceptive use among teenagers in the United States and provide an overview of OTC access to OCPs. In addition, this chapter will explore the evidence surrounding the safety and feasibility of moving OCPs OTC, including the advantages and disadvantages of removing the prescription requirement.

Unintended Pregnancy and Contraceptive Use Among Teenagers

Over half of all pregnancies in the United States are unintended, with Black and Hispanic women experiencing higher rates of unintended pregnancy (91 and 82 per 1000, respectively) compared to non-Hispanic White women (36 per 1000) (Finer & Zolna, 2011). Unintended pregnancy has numerous adverse health impacts, including delayed uptake of prenatal care, smoking and drinking during and after pregnancy, reduced breastfeeding, and premature birth (Cheng et al., 2009; Gipson et al., 2008; Kost & Lindberg, 2015). Further, continuing with an unwanted pregnancy is associated with experiencing physical, psychological, and sexual abuse during childhood and physical violence during pregnancy (Dietz, 1999; Gazmararian et al., 1995; Goodwin, Gazmararian, Johnson, Gilbert, & Saltzman, 2000). The public health challenge of unintended pregnancy is greatest among teenagers age 15-19, who have the highest rate of unintended pregnancy among all sexually active women (Finer, 2010).

Nonuse or inconsistent use of contraception accounts for approximately 95% of unintended pregnancies (Guttmacher Institute, 2015b). Although contraceptive use among teenagers has increased over the last 20 years (Martinez, Copen, & Abma, 2011), compared to older women of reproductive age, teenagers aged 15-19 have the highest proportion of
contraceptive nonuse (Mosher & Jones, 2010). In 2013, 86% of sexually active students in grades 9-12 reported using a contraceptive method at last sex; 59% reported using a male condom and 19% reported using OCPs (The National Campaign to Prevent Teen and Unwanted Pregnancy, 2014). Black students were significantly more likely to use condoms (65%) compared to non-Hispanic White (57%) and Hispanic students (58%), whereas non-Hispanic White students were significantly more likely to use OCPs (26%) compared to Black (8%) and Hispanic students (9%).

Lack of access to contraception has been cited as a primary reason for contraceptive nonuse among teenagers experiencing an unintended pregnancy (Centers for Disease Control and Prevention, 2012). Barriers accessing contraception, including financial and time constraints, lack of transportation or health insurance, and inaccessible healthcare provider and pharmacy locations can lead to gaps in teenagers’ contraceptive use and increase their risk of unintended pregnancy (Brindis & Davis, 1998; Dennis & Grossman, 2012; Frost, Singh, & Finer, 2007; Hock-Long et al., 2003; National Institute for Reproductive Health; Smith & Oakley, 2005). Further, concerns about parental disclosure of confidential information and laws that mandate parental notification or consent for contraceptive services are two unique age-related barriers that can impede teenagers’ contraceptive access (Brindis & Davis, 1998; Guttmacher Institute, 2015a; Hock-Long et al., 2003; Oberg et al., 2002).

**Over-the-Counter Access to Oral Contraceptive Pills**

Removing the prescription requirement for OCPs has been recommended as an approach to reduce unintended pregnancy and increase contraceptive access. Several medical organizations - including the American Congress of Obstetricians and Gynecologists, the
American Medical Association, the American Academy of Family Physicians, and the Women’s Health Practice and Research Network of the American College of Clinical Pharmacy - have issued statements in support of removing the prescription requirement after reviewing the risks and benefits of OTC access (American Academy of Family Physicians, 2014; American College of Obstetricians and Gynecologists, 2012; American Medical Association, 2013; McIntosh et al., 2011).

While OTC access to OCPs may seem like a novel concept in the United States, OCPs are available without a prescription in the majority of countries worldwide. A survey of government officials and pharmaceutical and reproductive health specialists in 147 countries found that OCPs were available informally without a prescription in 38% of countries; legally without a prescription in 24% of countries; and legally without a prescription, but with a screening from a healthcare provider in 8% of countries (Grindlay, Burns, & Grossman, 2013).

In addition to being widely available worldwide without a prescription, OCPs meet all of the U.S. Food and Drug Administration’s (FDA) criteria for moving a medication OTC (Britt Wahlin, 2014; Grossman & Fuentes, 2013): 1) they have no toxicity if overdosed; 2) they are not addictive; 3) a woman can independently determine if the pill is appropriate for her (i.e., whether she wants to prevent pregnancy); 4) a woman can take the medication as instructed without a healthcare provider’s explanation (i.e., take one pill every day) and; 5) a woman can independently determine if the medication is safe for her to use. Several safety and feasibility considerations of removing the prescription requirement for OCPs are discussed in detail below.
Safety of Over-the-Counter Access to Oral Contraceptive Pills

One of the main issues surrounding OTC access to OCPs is whether a woman can determine if the medication is safe for her to use without screening from a healthcare provider; this is one of the FDA’s criterion for moving a medication OTC. OCPs, which have over 50 years of research documenting their safety and efficacy, are one of the best-studied medications available on today’s market. An estimated 82% of all U.S. women will use OCPs at some point in their lives (Daniels & Mosher, 2013), including many women that use OCPs for non-contraceptive benefits, such as reducing heavy periods or severe cramping, acne, symptoms of polycystic ovarian syndrome, and benign breast masses (Dayal & Barnhart, 2001).

Although OCPs are safe for most reproductive aged women, women with specific medical conditions or characteristics have contraindications to OCP use. The Centers for Disease Control and Prevention’s Medical Eligibility Criteria for Contraceptive Use outlines conditions that are relative and absolute contraindications to OCPs (categories 3 and 4, respectively) (Centers for Disease Control and Prevention, 2010). For combined oral contraceptives (COCs), these include hypertension, migraine with aura, deep venous thrombosis or pulmonary embolism, being a smoker and age 35 years or older, stroke, and breast cancer, among others. Compared to COCs, progestin only pills (POPs) have fewer contraindications to use. In addition, the most common contraindications of COC use – hypertension, migraine with aura, and smoking among women 35 and older – are not contraindications of POP use (Centers for Disease Control and Prevention, 2010; Grossman et al., 2008; Grossman et al., 2011; Shortridge & Miller, 2007). Given that POPs have fewer contraindications to use, it is likely that a POP will be the first OCP to go OTC (White et al., 2012).
Prevalence of Contraindications

Several studies have sought to estimate the prevalence of U.S. women that have contraindications to OCPs. A 2014 study of 1,010 women desiring a combined hormonal contraceptive method (i.e., COC, patch, or ring) found that only 2% of women had a confirmed medical contraindication (Xu, Eisenberg, Madden, Secura, & Peipert, 2014). Study participants were on average 24 years old; therefore, the findings do not necessarily reflect the prevalence of contraindications in older women, which are generally higher. Additionally, a 2006 analysis of National Health and Nutrition Examination Survey (NHANES) data explored the prevalence of contraindications to COCs among current COC users and nonusers (Shortridge & Miller, 2007). Overall, 16% of women had conditions that were contraindicated to COC use: 6% of current users and 19% of nonusers. However, the NHANES did not collect information on women with thrombotic conditions or migraine with aura, two contraindications to COC use. Likewise, this study may underestimate the true prevalence of contraindications to COCs among U.S. women.

Finally, a study of 1,271 women of reproductive age from El Paso, Texas found that 39% of women had conditions that were contraindications for COC use (Grossman et al., 2008). Although this number is quite high compared to the previous studies, this study population was older (mean 32.6), which increases the chances of having a contraindication to COCs, and most women were not COC users, who likely would have already been screened for contraindications by a healthcare provider.

In addition, two studies of women living along the U.S.-Mexico border estimated the prevalence of contraindications to POPs (White et al., 2012). The first study included 1,046 current OCP users who obtained their pills OTC from Mexican pharmacies (n=514) and at clinics in El Paso, Texas (n=532). Among current OCP users, less than 1% self-reported having
any conditions that were contraindications for POP use. In the second study of 1,267 reproductive aged women from the general population in El Paso, Texas, less than 2% of women self-reported having any conditions that were contraindications for POP use. These studies demonstrate that the prevalence of contraindications to POP use is less than the prevalence of contraindications to COC use.

Women’s Abilities to Self-Screen for Contraindications

Research suggests that women who obtain OCPs OTC may have similar health profiles to women who obtain OCPs from a healthcare provider. Two studies from Mexico, where women can buy OCPs without a prescription, found that OTC and clinic users had a similar prevalence of contraindications to OCP use (Yeatman, Potter, & Grossman, 2006; Zavala et al., 1987). Additionally, findings from a study of women living along the U.S.-Mexico border found that the prevalence of contraindications to OCP use was not significantly different among women who obtained OCPs OTC at Mexican pharmacies and those who obtained OCPs at U.S. clinics (Grossman, Fernandez, Hopkins, Amastae, & Potter, 2010). These studies suggest that women who obtain OCPs OTC may be able to self-screen for contraindications as accurately as healthcare providers.

Two studies in the United States have explored the accuracy of women using a checklist to self-screen for contraindications compared to a healthcare provider’s gold standard evaluation. In the first study, 399 women age 15-45 completed a self-administered questionnaire about their medical history to determine whether OCPs were safe for their use (Shotorbani et al., 2006). Each woman’s healthcare provider also completed a medical evaluation and participant-provider agreement was calculated. The proportion of overall agreement was 96%. Compared to
healthcare providers, women were less likely to report irregular periods or smoking more than 15 cigarettes per day, but were more likely to report possible pregnancy, severe headaches, and smoking.

In a study of 1,271 OCP users and non-users living along the U.S.-Mexico border, researchers also sought to estimate the accuracy of women’s self-assessments of contraindications to OCP use (Grossman et al., 2008). Women were first asked whether they thought OCPs were safe for them to use (unaided self-assessment) and then were provided with a medical screening checklist (aided self-assessment). Both of these self-assessments were compared to an evaluation by a nurse practitioner. For the unaided self-assessment, the sensitivity to detect true contraindications was 56.2% and the specificity was 57.6%. For the aided self-assessment, the sensitivity to detect true contraindications was 83.2% and the specificity 88.8%. Using the aided self-assessment, 6.6% of women thought they were eligible for OCP use when they were contraindicated and 7% of women thought they were contraindicated to OCP use when they were eligible. Covariates associated with being more likely to accurately self-screen included younger women, Spanish speakers, and educated women.

Both of these studies show that using a self-screening tool is accurate in detecting contraindications to OCP use and women may not need a healthcare provider to determine if OCPs are safe for their use. Importantly, screening from a healthcare provider for contraindications, the gold standard, is not perfect: in the NHANES analysis of the prevalence of contraindications to COCs, 6% of current OCP users, who presumably should have already been evaluated for contraindications by a healthcare provider, were found to have contraindications to OCPs (Shortridge & Miller, 2007).
Contraceptive Continuation Among Over-the-Counter Users

Another important consideration about OTC access to OCPs is how removing the prescription requirement will impact women’s method continuation and adherence. A U.S. cohort study of 1,046 women living along the U.S.-Mexico border found that OCP continuation increased with OTC access (Potter et al., 2011). Over a 9-month period, OCP discontinuation was higher among women who obtained OCPs from clinics in Texas (25.1%) compared to women who obtained OCPs OTC in Mexican pharmacies (20.8%) (hazard ratio 1.6). Discontinuation rates were only similar among OTC and clinic users when comparing OTC users to clinic users who were dispensed 6 or more pill packs at a time. This finding indicates that access to multiple pill packs may also increase method continuation.

Attitudes Toward Over-the-Counter Access to Oral Contraceptive Pills

Healthcare Providers’ Attitudes

Although several medical organizations have issued statements in support of OTC access to OCPs (American Academy of Family Physicians, 2014; American College of Obstetricians and Gynecologists, 2012; American Medical Association, 2013; McIntosh et al., 2011), limited research suggests that some healthcare providers may have concerns about OTC access to OCPs. Given that healthcare providers are the primary prescribers of OCPs, they are important stakeholders in efforts to move OCPs OTC. While there is little data on healthcare providers’ perspectives, a survey of residents training in Family Practice and Obstetrics and Gynecology found that the majority (71%) of participants were against moving a COC OTC; ninety-two percent of those against OTC access reported safety as their primary concern (Howard, Wall, & Strickland, 2013). Participants were more supportive of OTC access to POPs, but were still
largely concerned about safety. An important limitation of this study is the response rate of 4%. Regardless, this study provides some insight into providers’ perspectives of OTC access and suggests that some healthcare providers may be misinformed about the safety of OCPs, given the previously described literature on OCP safety and the prevalence of contraindications to OCP use among women of reproductive age.

Women’s Attitudes

Another important consideration of moving OCPs OTC is whether women support OTC access and would use OCPs OTC. A nationally representative survey of 2,046 adult women at risk of unintended pregnancy sought to estimate the proportion of U.S. women who support and would be likely to use OTC OCPs (Grossman et al., 2013). Sixty-two percent of women reported supporting OTC access and 37% reported that they would be likely to use OTC OCPs.

Covariates associated with higher odds of supporting OTC access included: living with a partner (OR: 1.8) or never having married (OR: 1.6) (versus married) and having unprotected sex in the last 3 months (OR: 1.6). Current OCP users (OR: 6.2), less effective method users (OR: 2.2), and contraceptive non-users (OR: 1.7) had significantly higher odds of being interested in using OTC OCPs compared to women currently using an intrauterine device (IUD) or hormonal contraceptive other than OCPs. Additional covariates associated with higher odds of being interested in using OTC OCPs included: 1) living in the South (OR: 1.6) (versus the Northeast); younger age (OR: 2.1); being divorced/separated (OR: 2.3) or living with a partner (OR: 1.6) (versus married); and being uninsured (OR: 2.5) or having private insurance (OR: 1.7) (versus public insurance).
Several other studies have sought to explore women’s support and interest in OTC access. A 2011 survey of 651 abortion clients age 15-44 found that 81% of women supported removing the prescription requirement for OCPs and 61% would be likely to use OTC OCPs (Grindlay et al., 2014). Women who were Black (OR: 0.4) (versus White) and without a high school degree (OR: 0.4) (versus college degree) were less likely to support OTC access; women who had previously used OCPs (OR: 1.6) or planned to use OCPs after their abortion (OR: 2.2) (versus LARCs) were more likely to support OTC access. Covariates associated with increased odds of being interested in using OTC OCPs included: being uninsured (OR: 1.5) (versus public insurance); previous use of OCPs (OR: 1.4); having experienced difficulties getting an OCP prescription refill (OR: 2.7); intention to use OCPs after their abortion (OR: 13.0); and being age 20-29 or 30-46 (versus 15-19) (OR: 1.6, 1.8 respectively).

A 2006 study of 601 women 18-49 living along the U.S.-Mexico border also found high levels of interest in OTC access (Grossman et al., 2010). Sixty percent of women not currently using contraception or a hormonal method reported being likely to use OCPs if they were available OTC. Finally, in a 1997 survey of 251 female undergraduate students, 65% of women reported that OCPs should not be available without a prescription (Forman, Emans, Kelly, Beal, & Goodman, 1997); women experiencing a prior pregnancy had higher odds of supporting OTC access (OR: 3.68). While support for OTC access is low compared to the aforementioned studies (Grindlay et al., 2014; Grossman et al., 2013), in the years since this study was conducted many drugs, including EC, have become available OTC and women’s opinions about OTC access may have changed (US Food and Drug Administration, 2013).
Teenagers and Over-the-Counter Access

There is limited research on teenagers and OTC access to OCPs. One study of abortion clients’ attitudes toward OTC access to OCPs included teenagers in the study population (Grindlay et al., 2014). The researchers found that approximately 69% of 15-17 year olds supported OTC access to OCPs and 47% were likely to use an OTC OCP. While this study provides important information on teenagers and OTC access, levels of support and interest for OTC access may differ in this population, as teen abortion clients may have different experiences accessing contraceptive care than other teenagers.

Three recent studies on women’s attitudes toward OTC access to OCPs highlight that some women have concerns about teenagers’ access to OTC OCPs. A qualitative study of low-income women found that participants reported being worried that STD rates would increase among teenagers due to a decrease in condom use and that teenagers would not contact a healthcare provider if they experienced side effects while using OCPs (Dennis & Grossman, 2012). Further, in a survey of women’s attitudes toward OTC access to OCPs, 47% of women reported that one of their concerns was that “teens might have sex earlier or more often if it’s easy to get birth control” (Grossman et al., 2013).

A 2015 survey of a nationally representative sample of women at risk of unintended pregnancy found that women have mixed opinions about whether OTC OCPs should be available without a prescription for women under age 18 (Grindlay & Grossman, 2015). A total of 26% of women supported an age restriction for an OTC OCP; 28% of women were against an age restriction; and 46% of women were unsure.
Advantages and Disadvantages of Over-the-Counter Access

Women report a range of benefits to OTC access to OCPs, including that it would be easier or more convenient to get OCPs, that there would be fewer unwanted or teenage pregnancies, and that it would save time and money to not have to visit a healthcare provider (Dennis & Grossman, 2012; Forman et al., 1997; Grindlay et al., 2014; Grossman et al., 2013; Potter, White, Hopkins, Amastae, & Grossman, 2010). At the same time, women have also expressed concerns about moving OCPs OTC. Primary among these concerns is safety; research suggests that women are worried about other women’s abilities to choose the “right” pill and correctly use OCPs without a healthcare provider’s supervision (Dennis & Grossman, 2012; Forman et al., 1997; Grindlay et al., 2014; Grossman et al., 2013). A qualitative study of low-income women living in Boston highlighted that safety concerns center on teens, first-time OCP users, and women with medical contraindications (Dennis & Grossman, 2012).

In addition to concerns about safety, women report fears that OTC access will lead to women forgoing preventive health services, such as annual exams, cervical cancer screening, and STI testing (Dennis & Grossman, 2012; Forman et al., 1997; Grossman et al., 2013). However, a 2012 study of U.S. women who obtained their OCPs OTC in Mexican pharmacies and in U.S. clinics found that both groups of women reported high preventive health screening rates (Hopkins, Grossman, White, Amastae, & Potter, 2012). Additionally, although STI testing and cervical cancer screening are often linked with the provision of OCPs, many women’s health experts argue that these preventive health services are not necessary for OCP use (American College of Obstetricians and Gynecologists, 2012). Further, in 2012, recommendations for cervical cancer screening changed from annual testing to testing every three years (U.S. Preventive Services Task Force, 2012).
Cost of OTC Access to OCPs

Women also report concerns about the cost of OTC OCPs and whether health insurance will cover OCPs bought OTC (Dennis & Grossman, 2012; Grossman et al., 2013). In a 2010 study of U.S. women who obtained OCPs OTC in Mexican pharmacies, 40% of OTC users reported that cost was the primary advantage of obtaining OCPs OTC (Potter et al., 2010). This finding suggests that cost is an important determinant of whether women will use OTC OCPs and an increase in cost may outweigh the perceived benefits of OTC access. Indeed, a study of low-income women from Boston found that while most women were supportive of OTC access they would not want to pay more for the convenience of an OTC product (Dennis & Grossman, 2012).

Several studies have explored how much women would be willing to pay for an OTC OCP. In a 2011 survey of abortion clients, women who reported being likely to use an OTC OCP reported that they would be willing to pay an average of $21 per pill pack (median $20) (Grindlay et al., 2014). Of note, 20% of women reported they would not be willing to pay any amount for an OTC OCP. The amount of money women report being willing to spend is similar in other studies (Grossman et al., 2013). An observational cohort study of women’s out of pocket expenditures for OCPs between 1996 and 2006 found that women spent on average $16 per pill pack ($10 median) (Liang, Grossman, & Phillips, 2011). In combination, these studies suggest that women may be willing to pay $5-10 more per pack for OTC access.

Over-the-Counter Access to Oral Contraceptive Pills under the Affordable Care Act

Concerns about cost are of particular relevance given the new U.S. healthcare landscape. Under the Affordable Care Act (ACA) most insurance plans are required to cover the full range
of FDA approved contraceptives with no cost sharing (Healthcare.gov); this includes OTC methods, like EC and female condoms. While this technically means that insurance plans should cover OTC OCPs, Health and Human Services (HHS) has also stated that insurers can require women to get a prescription for OTC methods, negating the OTC benefit. Some state Medicaid programs currently allow women to use their insurance for OTC EC without a prescription (Britt Wahlin, 2014); women's health advocates have called for expanding this model to OTC OCPs and for HHS to remove “as prescribed” from the contraceptive requirement (American Public Health Association, 2011; Britt Wahlin, 2014).

Given that insurers can require a prescription for OTC methods and that women do not have a copay for contraception under the ACA, this begs the question of whether an OTC OCP will still be relevant. Research suggests that there are many women who would still benefit from OTC OCPs. First, many women will remain uninsured under the ACA (Buettgens, 2011). Research on women's access to contraception after Massachusetts health care reform highlights that many populations fell through the cracks, such as immigrants, young women, and women going through common life transitions such as moving or pregnancy (Ibis Reproductive Health & Massachusetts Department of Public Health Family Planning Program, 2009). Further, some insurance plans and employers are exempt from the ACA’s contraceptive mandate, including grandfathered plans, public insurance plans, and certain religious institutions (Healthcare.gov).

In addition, an OTC product would be beneficial to the many insured and uninsured women who run out of OCPs while traveling or on vacation. Research suggests that nearly a third of women using OCPs experience challenges obtaining or refilling a prescription (Landau, Tapias, & McGhee, 2006) and running out of OCPs is a main reason for inconsistent OCP use (Smith & Oakley, 2005). Further, OTC OCPs may be particularly beneficial to teenagers on their
parents’ health insurance plans who want to pay out of pocket for OCPs to ensure confidentiality (Covarrubias, 2013).
Chapter 3: Manuscript

Title Page for Manuscript:

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A Survey of Teenagers’ Attitudes Toward Moving Oral Contraceptives Over the Counter

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Contribution of Student:

Ms. Manski was responsible for writing the grant proposal and receiving funding for the study; developing the survey instrument; obtaining IRB approval; managing participant recruitment; conducting data analysis; and leading authorship of the manuscript.
Abstract

Context
Evidence suggests that over-the-counter access to oral contraceptives may improve contraceptive access and use among adult women. Teenagers may particularly benefit from over-the-counter access, as they experience disproportionately high rates of unintended pregnancy and face unique challenges accessing contraception. However, limited research has explored teenagers’ attitudes toward over-the-counter access.

Methodology
During September 2014, 348 females aged 14-17 were recruited via Facebook advertisements to participate in an online survey to assess teenagers’ attitudes toward over-the-counter access and understanding of how to use oral contraceptives based on reading a prototype over-the-counter product label. Descriptive statistics and bivariate analyses were conducted using SPSS; Pearson chi-square and Fisher’s exact tests were conducted for categorical outcomes and independent t-tests and one-way ANOVA for continuous outcomes.

Results
Seventy-three percent of participants reported being in favor of over-the-counter access and 61% reported that they would be likely to use oral contraceptives through over-the-counter access. Participants who had sex were significantly more likely to be interested in using over-the-counter access (77%) compared to participants who had not had sex (48%). Participants understood an average of 7.1 of 8 key concepts that the prototype over-the-counter product label was intended to convey; no significant differences were found among subgroups.

Discussion
Participants in this sample are interested in using oral contraceptives over the counter and can understand how to use an over-the-counter product. These findings, in combination with evidence documenting the safety and effectiveness of over-the-counter access, support continued exploration of recategorization of oral contraceptives to over-the-counter status without age restriction.
Introduction

Unintended pregnancy among teenagers in the United States (U.S.) is an important public health issue, as 82% of pregnancies in women 15-19 are unintended (Finer & Zolna, 2011). Inconsistent use or nonuse of contraception accounts for the majority of unintended pregnancies (Guttmacher Institute, 2015b), with lack of access to contraception being a main reason for contraceptive nonuse among teenagers experiencing an unintended pregnancy (Centers for Disease Control and Prevention, 2012). Barriers accessing contraception, including cost, lack of transportation or health insurance, inaccessible healthcare provider and pharmacy locations, and confidentiality concerns can lead to gaps in teenagers’ contraceptive use and increase their risk of unintended pregnancy (Brindis & Davis, 1998; Hock-Long et al., 2003; Oberg et al., 2002). Strategies to increase contraceptive access and use among this population are needed.

Removing the prescription requirement for oral contraceptives has been recommended as an approach to reduce unintended pregnancy and increase contraceptive access among U.S. women. Several medical organizations, including the American Congress of Obstetricians and Gynecologists, have issued statements in support of removing the prescription requirement, citing the safety and effectiveness of over-the-counter access (American College of Obstetricians and Gynecologists, 2012; American Medical Association, 2013; McIntosh et al., 2011). Studies on women’s attitudes toward over-the-counter access demonstrate that women support and are interested in over-the-counter access. In 2011, a nationally representative survey of 2,046 adult women at risk of unintended pregnancy found that 62% of women were in support of over-the-counter access and 37% of women reported being likely to use oral contraceptives through this method (Grossman et al., 2013). Additionally, research shows that women believe over-the-counter access would make it easier and more convenient to get oral contraceptives, reduce
unwanted pregnancies, and save women time and money by not having to visit a healthcare provider (Dennis & Grossman, 2012; Forman et al., 1997; Grindlay et al., 2014; Grossman et al., 2013; Potter et al., 2010).

Teenagers may particularly benefit from over-the-counter access, as they experience disproportionately high rates of unintended pregnancy and face unique challenges accessing contraception (Brindis & Davis, 1998; Finer, 2010; Finer & Zolna, 2011; Hock-Long et al., 2003). A 2011 survey of 651 women seeking abortion care at 6 U.S clinics found that 69% of 15-17 year olds supported over-the-counter access and 47% reported they would be likely to use oral contraceptives through this method (Grindlay et al., 2014). However, little data exist regarding attitudes toward over-the-counter access among teens not seeking abortion care. Additionally, research has not yet explored whether teenagers can understand how to correctly use oral contraceptives based on reading an over-the-counter product label; studies indicate that this is a concern among adult women (Dennis & Grossman, 2012; Grindlay & Grossman, 2015; Grossman et al., 2013).

Given the recent concerns around removing the prescription requirement for Plan B emergency contraception without age restriction (US Food and Drug Administration, 2013), any efforts to move oral contraceptives over the counter will likely generate similar discussions surrounding teenagers’ access to an over-the-counter product. Research on teenagers and over-the-counter access can help inform future policy decisions about whether to move oral contraceptives over-the-counter without age restriction. As such, the aims of this study were to assess female teenagers’: 1) attitudes toward oral contraceptives being available for teenagers through over-the-counter access and 2) understanding of a prototype over-the-counter product label.
Methods

Survey design and sample

During September 2014, females aged 14-17 were recruited via Facebook advertisements to participate in an online survey. Facebook has been shown to be an effective recruitment tool for adolescent health research (Amon, Campbell, Hawke, & Steinbeck, 2014) and the majority of teenagers age 14-17 use Facebook (Pew Research Center, 2014); additionally, the distribution of Facebook users by race and ethnicity is estimated to be similar to that of the U.S. population (Marlow, 2009). Facebook advertisements were targeted to only appear on the Facebook pages of females, aged 14-17 years, living in the United States. The target population excluded teenagers aged 18-19 because they have different opportunities for contraceptive access than younger teens, who are minors (Guttmacher Institute, 2015a). The Facebook advertisements were paid for using a “cost per click” strategy where a cost was incurred each time the advertisement was clicked, regardless of consent or participation in the study. The average cost per advertisement click was $0.52 and the average cost per complete survey was $5.98, as not all people who clicked on the advertisement completed the survey.

The Facebook advertisement included a brief description of the study and prompted interested users to click for more information. Upon clicking the advertisement, participants were directed to an online survey, created through REDCap, where they were given information about the purpose of the study and screened for eligibility. In order to participate, participants had to be: 1) age 14-17; 2) female; and 3) proficient in reading and writing English. All eligible participants were provided with an assent form detailing the research project and asked to electronically indicate their assent to participate. A waiver of parental consent was obtained and the study protocol was approved by the Emory University Institutional Review Board. All
participants that completed the online survey and provided an email address received a $5 Amazon gift card.

Measures

The survey instrument was developed after reviewing the literature on over-the-counter access and consulting with subject matter experts. The survey instrument was then reviewed in-person with three teen peer educators to ensure comprehension of survey questions and piloted with 35 Facebook users (recruited using the same eligibility criteria described above) to validate the data collection process. Participants were asked about their age, race and ethnicity, health insurance status, education level, state of residence, and whether they lived in a rural, suburban, or urban area. Questions about participants’ sexual and reproductive characteristics included whether participants had ever had sex (defined as penile/vaginal sexual intercourse), ever used any type of contraception (including ever use of oral contraceptives), ever been pregnant, and ever been tested for sexually transmitted diseases (STDs).

Participants were also asked about their attitudes toward oral contraceptives being available for teenagers through over-the-counter or pharmacy access. The term “teen” was used in the survey instrument and was intended to refer to individuals of the same age group as the study participants, though this was not defined. Over-the-counter access was described as: “Teens could buy birth control pills at a drugstore or grocery store, just like vitamins or shampoo. Teens wouldn’t need a prescription and wouldn’t need to talk to anyone about buying birth control pills (not a doctor, pharmacist, or parent) unless they wanted to. Health insurance may or may not cover the cost of birth control pills bought over the counter.” Pharmacy access was described as: “Teens could buy birth control pills from a pharmacist (someone that gives out medicine) at a drugstore or grocery store. Teens wouldn't need a prescription, but they
would need to ask the pharmacist for birth control pills and answer some questions about their health before getting the pills. Health insurance may or may not cover the cost of birth control pills bought through pharmacy access.”

In addition, participants were asked about their support for over-the-counter and pharmacy access to oral contraceptives. Participants were considered to support over-the-counter or pharmacy access if they reported being strongly or somewhat in favor of over-the-counter or pharmacy access (as opposed to strongly or somewhat against, not sure, or prefer not to answer). Participants were considered likely to use over-the-counter or pharmacy access if they reported being very or somewhat likely to use over-the-counter or pharmacy access (as opposed to very or somewhat unlikely, not sure, not interested in using birth control pills, or prefer not to answer).

Participants were asked what is the highest price they would be willing and able to pay for each month’s supply of birth control pills obtained over-the-counter and through pharmacy access. Participants could select $0, a five-dollar price range beginning at $1-5 and ending at $46-50, or $51+. Finally, for over-the-counter access, participants were asked to indicate the one biggest advantage and disadvantage of this approach. Participants were given a list of options identified in previous research as reasons why women support or oppose over-the-counter access (Dennis & Grossman, 2012; Grindlay et al., 2014; Grossman et al., 2013), or could write in their own responses. Examples of provided options included “fewer teens would get pregnant” (advantage) and “teens might not use condoms to protect against STDs” (disadvantage).

The survey also included questions assessing comprehension of a prototype over-the-counter product label1 for a progestin-only pill (POP). A POP product label was selected because

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1 The Oral Contraceptives Over the Counter Working Group, a coalition of organizations, researchers, and clinicians committed to providing women with easier access to contraceptives, developed the product label by reviewing the Food and Drug Administration’s requirements for an over-the-counter Drug Facts label; the United States Medical Eligibility Criteria for Contraceptive Use; and the norethindrone prescription POP product label.
POPs have fewer medical contraindications to use and would likely be the first type of oral contraceptive to move over the counter (White et al., 2012). Participants were asked to read the product label and answer eight closed-ended questions about eight key concepts that were determined to be important for safe and effective use of POPs. Examples of questions and key concepts included: “Katie used this pill because she wanted to be sure she didn’t get any STDs or HIV. Was this a correct use of this pill?” (Key concept: POPs do not prevent STDs or HIV) and “Destiny vomited 1 hour after taking this pill. She takes another pill as soon as she can. Was this a correct use of this pill?” (Key concept: Take another pill immediately if vomiting occurs within 2 hours of taking POPs). Participants could refer to the product label while answering questions.

Analysis

All statistical analyses were conducted in SPSS version 22.0. Primary outcomes related to participants’ attitudes were support for over-the-counter access and likelihood of over-the-counter use; secondary outcomes were support for pharmacy access and likelihood of pharmacy access use. For the label comprehension component of the survey, the primary outcome was the mean number of key concepts understood by participants. Bivariate analyses were conducted on characteristics (i.e., demographics, ever use of oral contraceptives) that have previously been found to have an association with study outcomes (Grindlay et al., 2014; Grossman et al., 2013; Landau et al., 2006), as well as other characteristics that were measured in the survey. Pearson chi square and Fisher’s Exact tests were conducted between demographic and reproductive characteristics and categorical outcome variables to determine any differences among subgroups; independent samples t-tests and one-way ANOVA were conducted for continuous outcomes. Participants who preferred not to answer to questions about their demographic and reproductive characteristics were excluded from analyses.
Results

Demographic and reproductive characteristics

The Facebook advertisements received 3,720 clicks; 482 participants consented to participate and 348 participants completed the survey. Results are only presented for participants that completed the survey, as demographic and reproductive characteristics are not available for other participants.

Thirty-two percent of participants were age 17, 31% were age 16, 24% were age 15, and 13% were age 14 (Table 1). The majority of participants identified as Non-Hispanic White (67%). Participants were from 44 states and the District of Columbia (not shown); no U.S. region predominated. Approximately half of participants reported living in a suburban area (53%). The majority of participants reported having health insurance: 41% reported having private insurance, 33% reported having public insurance, and 21% reported not knowing their type of insurance.

Forty-four percent of participants reported having ever had sex; among these participants, 60% reported having ever had unprotected sex, 90% reported having ever used contraception, 12% reported having ever been pregnant, and 44% reported having ever been tested for STDs (Table 1). Among contraceptive users, 58% of participants had used oral contraceptives.

Over-the-counter access

- Support

Overall, 73% of respondents reported being in favor of teenagers being able to access oral contraceptives over the counter (Table 2). Participants who had sex were significantly more likely to support over-the-counter access compared to those who had never had sex (85% vs. 63%, respectively). Additionally, participants who had never been tested for STDs were
significantly more likely to support over-the-counter access compared to those who had been tested for STDs (91% vs. 76%, respectively).

- **Likelihood of use**

  Sixty-one percent of respondents reported being likely to use oral contraceptives if they were available over the counter (Table 2). Participants who had sex were significantly more likely to report they would use oral contraceptives through over-the-counter access compared to participants who had never had sex (77% vs. 48%, respectively).

- **Willingness and ability to pay**

  Among participants likely to use oral contraceptives over the counter (n=212), 1% would not be willing and able to pay any amount for each month’s supply of oral contraceptives through over-the-counter access; 20% would pay $1-10; 43% would pay $11-20; 33% would pay $21 or more; and 4% were unsure how much they would pay (not shown).

- **Benefits and Concerns**

  Most commonly, participants reported that the greatest benefit to teenagers being able to get oral contraceptives over the counter is that fewer teenagers would get pregnant (45%) (Table 3). Other common responses included that it would be easier for teenagers to get birth control (22%) and it would be more confidential (14%). When asked their greatest worry about teenagers being able to get oral contraceptives over the counter, 22% of participants reported that teenagers might not use condoms to protect against STDs. Other common responses included that teenagers need a doctor to decide if birth control pills are safe for them (19%); teenagers might have sex at a younger age (18%); and teenagers might use birth control pills incorrectly (16%).

*Pharmacy access*
• **Support**

Overall, 79% of respondents reported being in favor of teenagers being able to access oral contraceptives through pharmacy access (Table 2). Participants who had sex were significantly more likely to support pharmacy access than participants who had never had sex (85% vs. 75%, respectively). In addition, participants who were from a suburban area were significantly more likely to support pharmacy access (87%) than participants who were from a rural (73%) or urban area (79%).

• **Likelihood of use**

A total of 57% of respondents reported being likely to use oral contraceptives if they were available through pharmacy access (Table 2). Participants who had sex were significantly more likely to report they would use oral contraceptives through pharmacy access than participants who had never had sex (73% vs. 44%, respectively).

• **Willingness and ability to pay**

Among participants likely to use oral contraceptives through pharmacy access (n=198), 3% reported they would not be willing and able to pay any amount for each month’s supply of oral contraceptives through pharmacy access; 16% would pay $1-10; 42% would pay $11-20; 36% would pay $21 or more; and 3% were unsure how much they would pay (not shown).

*Label comprehension*

On average, participants understood 7.1 of the 8 key concepts (not shown). The question that the most participants answered correctly (95%) described a scenario about use of oral contraceptives to prevent STDs and HIV; the question that the least participants answered correctly (63%) described a scenario about use of oral contraceptives when vomiting occurs.
(Table 4). The mean number of key concepts understood by participants was compared across subgroups outlined in Table 1. No statistically significant differences were found.

**Discussion**

Study results show that the majority of participants in this sample support and would use oral contraceptives through over-the-counter or pharmacy access. These findings echo previous studies that have shown that women are interested in accessing oral contraceptives through these methods (Dennis & Grossman, 2012; Grindlay et al., 2014; Grossman et al., 2013; Landau et al., 2006; Potter et al., 2010). Compared to a sample of teenage abortion clients, levels of support and interest in using over-the-counter access are higher among participants in this study (Grindlay et al., 2014). This may reflect that this sample is generally more interested in using oral contraceptives or the different demographic makeup of the two study populations.

Participants in this study were predominately non-Hispanic White and insured and had not experienced a previous pregnancy; this sample is likely at lower risk for unintended pregnancy than the predominantly Black, low-income population of abortion clients included in the former study.

The high levels of interest in using over-the-counter oral contraceptives among participants in this study and their perceptions of its many benefits – fewer teenage pregnancies, easier access to birth control, and increased confidentiality – highlight the potential of this strategy to reduce barriers teenagers face accessing contraception. At the same time, participants in this study reported concerns similar to those identified in other studies about teenagers’ access to over-the-counter oral contraceptives, including that teenagers would have sex earlier or stop using condoms and that teenagers need a healthcare provider to determine if oral contraceptives
are safe for their use (Dennis & Grossman, 2012; Grindlay et al., 2014; Grossman et al., 2013; Landau et al., 2006). Studies on over-the-counter emergency contraception demonstrate that easier access does not increase sexual risk taking behavior and teenagers can safely use over-the-counter emergency contraception (Atkins & Bradford, 2014; Harper, Cheong, Rocca, Darney, & Raine, 2005); however, teenagers’ behavior surrounding over-the-counter oral contraceptives may differ. Additionally, the majority of participants in this study reported they would not pay ≥$20 per month for over-the-counter access. The cost of an over-the-counter product will be an important determinant of whether teenagers use this method, as financial barriers accessing contraception are particularly pronounced among this population (Brindis & Davis, 1998; Hock-Long et al., 2003; Oberg et al., 2002).

This study found that the majority of surveyed participants understood the key concepts that the prototype over-the-counter product label was intended to convey. While levels of understanding were high, data do not predict how teenagers would use an over-the-counter product and such behaviors should be evaluated in an actual use study. Additionally, this study did not collect data on participants’ literacy levels, which could influence their understanding of key concepts and should be evaluated in future label comprehension studies.

This study has several limitations. First, participants were recruited through a convenience sample on Facebook and results cannot be generalized to the larger population. Participants were predominately non-Hispanic White and insured and may not represent teenagers at greatest risk for unintended pregnancy. Participants also had to choose to click on the Facebook ad and 13% who clicked on the ad enrolled in the study. While data on Facebook recruitment outcomes from adolescent health research show that this response rate is similar to other Facebook studies (Amon et al., 2014), this still may introduce selection bias. Second,
participants were asked hypothetical questions about their use of over-the-counter and pharmacy access. Participants’ future uptake of oral contraceptives through these approaches may differ. Finally, due to the small sample size and cell counts, this study only measured associations between sample characteristics and outcome variables; future studies would benefit from more extensive analyses that look at factors that may confound support or likelihood of use.

Despite these limitations, this study contributes new information on teenagers and over-the-counter and pharmacy access to oral contraceptives. Findings suggest that teenagers in this sample are interested in using oral contraceptives through these approaches and are able to answer questions about correct usage based on reading a prototype over-the-counter product label. Future research on over-the-counter and pharmacy access should include teenagers, as these provision models have the potential to impact teenagers’ access to and use of oral contraceptives.


Tables

Table 1. Percentage distribution of participants by sample characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (N=348)</th>
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<tr>
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<td>--------</td>
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1 Includes >1 race, Native Hawaiian and Pacific Islander, American Indian and Alaska Native, and other write in response
2 Among participants who had sex
Table 2. Percentage distribution of participants who support and are likely to use oral contraceptives through over-the-counter and pharmacy access, by sample characteristics (N=348)

<table>
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<th>Pharmacy access</th>
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<td>Likely to use</td>
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</tr>
<tr>
<td>Other¹, Non-Hispanic</td>
<td>75.7</td>
<td>59.5</td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>72.8</td>
<td>63.2</td>
</tr>
<tr>
<td>Hispanic</td>
<td>71.1</td>
<td>62.2</td>
</tr>
<tr>
<td><strong>Region</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwest</td>
<td>70.4</td>
<td>59.7</td>
</tr>
<tr>
<td>Northeast</td>
<td>72.2</td>
<td>66.7</td>
</tr>
<tr>
<td>South</td>
<td>73.4</td>
<td>63.8</td>
</tr>
<tr>
<td>West</td>
<td>71.4</td>
<td>55.2</td>
</tr>
<tr>
<td><strong>Geographical area</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>70.6</td>
<td>57.6</td>
</tr>
<tr>
<td>Suburban</td>
<td>74.7</td>
<td>63.5</td>
</tr>
<tr>
<td>Urban</td>
<td>80.6</td>
<td>64.2</td>
</tr>
<tr>
<td><strong>Insurance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>81.0</td>
<td>66.0</td>
</tr>
<tr>
<td>Private</td>
<td>70.4</td>
<td>63.2</td>
</tr>
<tr>
<td>Yes, but don’t know insurance type</td>
<td>81.3</td>
<td>62.5</td>
</tr>
<tr>
<td>No</td>
<td>61.1</td>
<td>66.7</td>
</tr>
<tr>
<td><strong>Ever had sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>84.7⁺</td>
<td>77.3⁺</td>
</tr>
<tr>
<td>No</td>
<td>62.8</td>
<td>47.9</td>
</tr>
<tr>
<td><strong>Ever had unprotected sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>85.1</td>
<td>81.6</td>
</tr>
<tr>
<td>No</td>
<td>86.4</td>
<td>72.9</td>
</tr>
<tr>
<td><strong>Ever used birth control²</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>86.6</td>
<td>79.9</td>
</tr>
<tr>
<td>No</td>
<td>73.2</td>
<td>60.0</td>
</tr>
<tr>
<td></td>
<td>Ever used oral contraceptives&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>84.4</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>89.5</td>
</tr>
<tr>
<td>Ever been pregnant&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Yes</td>
<td>72.2</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>86.8</td>
</tr>
<tr>
<td>Ever been tested for STDs&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Yes</td>
<td>76.2&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>91.4</td>
</tr>
</tbody>
</table>

<sup>1</sup> Includes >1 race, Native Hawaiian and Pacific Islander, American Indian and Alaska Native, or other write in response
<sup>2</sup> Among participants who had sex
<sup>*</sup> Differences among subgroups are significant at p<.05
Table 3. Percentage of participants reporting benefits of and concerns about over-the-counter access to oral contraceptives

<table>
<thead>
<tr>
<th>Greatest benefit of over-the-counter access (one response accepted)</th>
<th>Total (N=348)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer teens would get pregnant</td>
<td>44.5</td>
</tr>
<tr>
<td>Easier for teens to get birth control pills</td>
<td>22.4</td>
</tr>
<tr>
<td>It would be more confidential</td>
<td>13.5</td>
</tr>
<tr>
<td>It would feel less embarrassing</td>
<td>6.3</td>
</tr>
<tr>
<td>It would be more convenient</td>
<td>6.0</td>
</tr>
<tr>
<td>No advantages</td>
<td>4.6</td>
</tr>
<tr>
<td>Other(^1)</td>
<td>2.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Greatest worry about over-the-counter access (one response accepted)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Teens might not use condoms to protect against STDs</td>
<td>21.6</td>
</tr>
<tr>
<td>Teens need a doctor to decide if birth control pills are safe for them</td>
<td>18.7</td>
</tr>
<tr>
<td>Teens might have sex at a younger age</td>
<td>18.1</td>
</tr>
<tr>
<td>Teens might use birth control pills incorrectly</td>
<td>15.8</td>
</tr>
<tr>
<td>No disadvantages</td>
<td>7.2</td>
</tr>
<tr>
<td>Teens might not get tested for STDs</td>
<td>6.6</td>
</tr>
<tr>
<td>Birth control pills might cost more over the counter</td>
<td>5.5</td>
</tr>
<tr>
<td>Teens might not talk to their parents about birth control</td>
<td>4.6</td>
</tr>
<tr>
<td>Other(^2)</td>
<td>2.0</td>
</tr>
</tbody>
</table>

\(^1\) Other includes respondents who answered “don’t know,” “it would save time” or provided a write-in response

\(^2\) Other includes respondents who answered “don’t know,” or provided a write-in response
# Table 4. Percentage of participants that understand key concepts about product label

<table>
<thead>
<tr>
<th>Key concept</th>
<th>Total (N=348)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. POPs do not prevent STDs or HIV</td>
<td>94.8</td>
</tr>
<tr>
<td>2. POPs should not be used by individuals with allergy to any ingredient in the product</td>
<td>93.7</td>
</tr>
<tr>
<td>3. Condoms should be used for at least the first two days after starting POPs</td>
<td>92.5</td>
</tr>
<tr>
<td>4. Take another pill immediately if vomiting occurs within 2 hours of taking POPs</td>
<td>63.2</td>
</tr>
<tr>
<td>5. Users should contact a doctor immediately if they experience abdominal pain</td>
<td>86.5</td>
</tr>
<tr>
<td>6. POPs should be taken at the same time each day</td>
<td>92.5</td>
</tr>
<tr>
<td>7. Side effects of POPs include irregular periods</td>
<td>93.1</td>
</tr>
<tr>
<td>8. Use condoms or abstain from sex for 2 days if POP is taken ≥3 hours late</td>
<td>90.2</td>
</tr>
</tbody>
</table>
Chapter 4: Conclusions and Implications

Study results show that the majority of participants in this sample support and would use OCPs through OTC or pharmacy access. These findings echo previous studies that have shown that women are interested in obtaining OCPs through these provision models (Dennis & Grossman, 2012; Grindlay et al., 2014; Grossman et al., 2013; Landau et al., 2006; Potter et al., 2010). Compared to a sample of teenage abortion clients, levels of support and interest in using OTC access are higher among participants in this study (Grindlay et al., 2014). This may reflect that this sample is generally more interested in using OCPs or the different demographic makeup of the two study populations. Participants in this study were predominately non-Hispanic White and insured and had not experienced a previous pregnancy; this sample is likely at lower risk for unintended pregnancy than the predominantly Black, low-income population of abortion clients included in the former study (Guttmacher Institute, 2015b; Pazol et al., 2011).

Sexually active participants were significantly more likely to report they would OCPs through OTC access. This finding is encouraging given that this subgroup has a demonstrated need for contraception and may suggest that participants both understand this need and are open to accessing contraceptives OTC. Notably, there were no significant differences in likelihood of use among OCP users and non-users; this finding differs from previous research that has found use of OCPs to be a predictor of interest in OTC access (Grindlay et al., 2014; Grossman et al., 2013). Findings may highlight differences in teenagers’ and adult women’s contraceptive preferences and experiences. A 2011 survey of adult women at risk of unintended pregnancy found that the majority of OCP nonusers were not interested in using OCPs regardless of OTC status (Grossman et al., 2013), whereas in this study, only a minority of OCP nonusers reported they were not interested in using OCPs.
The high levels of interest in using OTC OCPs and participants’ perceptions of its many benefits – fewer teenage pregnancies, easier access to birth control, and increased confidentiality – highlight the potential of this strategy to reduce contraceptive access barriers, as well as unintended pregnancies. Previous research has identified that confidentiality and ease of access are important factors that impact teenagers’ decisions to use contraception (Daley, 2014); that participants perceive over-the-counter access to facilitate confidentiality and easier contraceptive access suggests that this approach could increase teenagers’ contraceptive use. Additionally, participants’ belief that OTC access could reduce teenage pregnancies speaks to the value of exploring this provision model further. A 2015 study estimated that making OCPs available OTC could reduce the number of unintended pregnancies among women aged 15-45 by 7-25% (Foster, Biggs, Phillips, Grindlay, & Grossman, 2015).

At the same time, participants reported concerns similar to those identified in other studies about teenagers’ access to OTC OCPs, including that teenagers need a healthcare provider to determine if OCPs are safe for their use and that teenagers would have sex earlier, stop using condoms, or use OCPs incorrectly (Dennis & Grossman, 2012; Grindlay et al., 2014; Grossman et al., 2013; Landau et al., 2006). Studies on OTC EC demonstrate that easier access does not increase sexual risk taking behavior and teenagers can safely use OTC EC (Atkins & Bradford, 2014; Harper et al., 2005); however, teenagers’ behavior surrounding OTC OCPs may differ.

Further, while only a minority of participants reported that cost was their greatest concern about moving OCPs OTC, the majority of participants reported they would not pay ≥$20 per month for OTC access. The cost of an OTC product will be an important determinant of whether teenagers actually use this method, as financial barriers accessing contraception are particularly
pronounced among this population (Brindis & Davis, 1998; Hock-Long et al., 2003; Oberg et al., 2002). Indeed, when EC went OTC in 2013, the high cost – anywhere between $26-$65 per product – made it out of reach for many women (American Society for Emergency Contraception, 2013). Policy solutions may be needed to keep the cost of an OTC product low and to ensure that teenagers have insurance coverage for OTC methods.

Finally, this study found that the majority of surveyed participants understood the key concepts that the prototype OTC product label was intended to convey and there were no significant differences among subgroups. This suggests that participants can understand how to effectively use OCPs with independent label review alone. These data offer some empirical evidence in response to concerns raised in this study and other studies about teenagers’ comprehension of OTC use (Dennis & Grossman, 2012; Grindlay & Grossman, 2015; Grossman et al., 2013). However, while results suggest that participants understand an OTC product label, data do not predict how teenagers would use an OTC product and such behaviors should be evaluated in an actual use study.

This study has several limitations. First, participants were recruited through a convenience sample on Facebook and results cannot be generalized to the larger population. Participants were predominately non-Hispanic White and insured and may not represent teenagers at greatest risk for unintended pregnancy. Participants also had to choose to click on the Facebook ad and 13% who clicked on the ad enrolled in the study. While data on Facebook recruitment outcomes from adolescent health research show that this response rate is similar to other Facebook studies (Amon et al., 2014), this still may introduce selection bias. Second, participants were asked hypothetical questions about their use of OTC and pharmacy access. Participants’ future uptake of oral contraceptives through these provision models may differ.
Next, this study did not collect data on participants’ literacy levels, which could influence their understanding of key concepts about the product label and should be evaluated in future label comprehension studies. Finally, due to the small sample size and cell counts, this study only measured associations between sample characteristics and outcome variables; future studies would benefit from more extensive analyses that look at factors that may confound support or likelihood of use.

Despite these limitations, this study fills an important gap in the existing literature on OTC to oral contraceptives. Data suggest that participants in this sample are interested in using OCPs OTC and can understand how to use an OTC product. These findings, in combination with existing evidence documenting the safety and effectiveness of OTC access, support continued exploration of reclassification of OCPs to OTC status without age restriction.
References:


   (2008). Accuracy of self-screening for contraindications to combined oral contraceptive 
   Perceptions of the safety of oral contraceptives among a predominantly Latina population 
   reproductive healthcare strategy. *Curr Opin Obstet Gynecol, 25*(6), 500-505. doi: 
   10.1097/gco.0000000000000019
   Interest in over-the-counter access to oral contraceptives among women in the United 
   Contraindications to combined oral contraceptives among over-the-counter compared 
   with prescription users. *Obstet Gynecol, 117*(3), 558-565. doi: 
   10.1097/AOG.0b013e31820b0244
   from https://guttmacher.org/pubs/fb_ATSRH.pdf
37. Guttmacher Institute. (2015a). Minors' access to contraceptive services from 
   http://www.guttmacher.org/statecenter/spibs/spib_MACS.pdf
   http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html


53. National Institute for Reproductive Health. Barriers to contraceptive access for low-income women from

http://www.nirhealth.org/sections/publications/documents/contraceptiveaccessquicksheet_FINAL.pdf


56. Pew Research Center. (2014). 6 new facts about Facebook. from

http://www.pewresearch.org/fact-tank/2014/02/03/6-new-facts-about-facebook/


64. US Food and Drug Administration. (2013). FDA approves Plan B One-Step emergency contraceptive for use without a prescription for all women of child-bearing potential. from [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm)


