



Original article

## Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women

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Article history: Received 2 July 2019; Received in revised form 18 December 2019; Accepted 17 January 2020

### ABSTRACT

**Objective:** To model the impacts of out-of-pocket cost of an over-the-counter (OTC) progestin-only pill on use and associated unintended pregnancy among U.S. women.

**Study Design:** Using data from a 2015 nationally representative survey of 2,539 U.S. women aged 15 to 44 assessing interest in using an OTC progestin-only pill, we used discrete survival analysis and a Markov model to analyze women's likelihood of using of an OTC pill at different price points and by sociodemographic characteristics. We modeled the impact of product price on the potential total number of U.S. users and on unintended pregnancies in 1 year among adult women at risk of unintended pregnancy.

**Results:** In a model assuming no out-of-pocket costs, more than 12.5 million adults and 1.75 million teens reported likely use of an OTC progestin-only pill if available. Among adults, this resulted in an estimated 8% decrease in unintended pregnancy in 1 year. Adult and teen women on average were willing to pay \$15 and \$10, respectively, resulting in 7.1 million adult and 1.3 million teen users and an estimated 5% decrease in unintended pregnancy among adults.

**Conclusions:** At low and no out-of-pocket cost, a large population of women in the United States might likely use an OTC progestin-only pill. A low retail price and insurance coverage are necessary to provide equitable access to this method for low-income populations across the United States, fill current gaps in contraceptive access, and potentially decrease unintended pregnancy.

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There is demonstrated interest in an over-the-counter (OTC) oral contraceptive in the United States. In 2011, a nationally representative study found 62% of U.S. adult women were in support of bringing an oral contraceptive OTC, and 37% were likely to use a product if it became available OTC (Grossman et al., 2013). In 2015, another nationally representative survey showed that 39% of adult women (aged 18–44) at risk of unintended pregnancy and 29% of teens (aged 15–17) were likely to use an OTC progestin-only oral contraceptive pill (POP) if one were

available (Grindlay & Grossman, 2018). Although all pills are safe and complications are rare, POPs are the most likely to become available OTC first because the absence of estrogen means they have fewer and rarer contraindications (White et al., 2012). Such a product has the potential to increase access to a highly effective contraceptive method for those who want to prevent pregnancy and thereby address one of the leading causes of unintended pregnancy, inconsistent or lack of contraceptive use (Jones, Darroch, & Henshaw, 2002; Sonfield, Hasstedt, & Gold, 2014).

Prior research has shown affordability of an OTC oral contraceptive is critical to its use among low-income populations (Foster, Biggs, Phillips, Grindlay, & Grossman, 2015). With the same failure rate as prescription oral contraceptives, one study predicted a 7%–25% decrease in unintended pregnancies among

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low-income women if the pill were available at no out-of-pocket cost (Foster et al., 2015). At higher out-of-pocket costs, benefits on unintended pregnancy decreased and interest in use decreased significantly (Foster et al., 2015). The study used data from a survey that did not specify pill type. Given the market predominance of combined oral contraceptives (COCs) (Liang, Grossman, & Phillips, 2012), the findings presented likely reflect interest in a COC, rather than POPs.

Although prior literature estimated use of an OTC OC at different out-of-pocket costs and the resulting potential impacts on unintended pregnancy among low-income U.S. women (Foster et al., 2015), no research has explored this topic for an OTC POP, modeled willingness to pay by sociodemographic characteristics, or modeled the impacts of OTC pill use on unintended pregnancy among the overall U.S. population of women at risk of unintended pregnancy. This study aims to fill these gaps by estimating the use of an OTC POP at different out-of-pocket price points and by background characteristics, and modeling the potential impacts of OTC POP use on unintended pregnancy among the U.S. population of adult women at risk of unintended pregnancy over a 1-year period. These findings will inform efforts related to insurance coverage and the pricing of an OTC pill if it becomes available in the United States.

## Methods

### Data

The primary source of data for this analysis was a nationally representative cross-sectional survey conducted in 2015 among 2,026 women aged 18 to 44 and 513 adolescent women aged 15 to 17. The survey explored interest in OTC access to a POP. Adult women aged 18 to 44 were eligible for the survey if they were at risk of unintended pregnancy (defined as not currently pregnant, not trying to get pregnant, not sterilized and did not have partners who were sterilized for contraceptive or non-contraceptive reasons, and had sex with a man in the past 12 months; Landau, Tapias, & McGhee, 2006). Adolescent women were eligible if they were not pregnant or currently trying to get pregnant. The number of adolescent participants who were sexually active adolescent at the time of the survey was small ( $n = 74$  [15.7%]). The survey was conducted through Growth from Knowledge's KnowledgePanel, a nationally representative, probability-based nonvolunteer online household panel (Knowledge Networks, 2013). The KnowledgePanel uses probability-based sampling to draw from addresses from the U.S. Postal Service's Delivery Sequence file. A laptop computer and Internet access were provided to panel members who lacked access. The panel members received incentives for their participation in surveys. The sample was drawn from active panel members using a probability-proportional-to-size weighted sampling approach. The survey was fielded in Spanish and English. The survey was weighted to demographic and geographic distributions for noninstitutionalized women aged 15 to 44 from the March 2014 Current Population Survey (Bureau of the Census for the Bureau of Labor Statistics, 2014) and Spanish language distributions from the 2013 American Community Survey (U.S. Census Bureau, 2013). We refer to this survey as the "POP interest survey."

This analysis also utilized the National Survey of Family Growth 2013–2015, a nationally representative survey of women aged 15–44 conducted by the National Center for Health Statistics (National Center for Health Statistics, 2016). The United States Census provided estimates of the female population

between the ages of 15–17 and 18–44 in 2015 (U.S. Census Bureau, Population Division, 2017).

### Analysis

#### *Probability of use of an OTC POP at different out-of-pocket costs*

We used a Markov model to estimate the probability that a given woman in the POP interest survey would use an OTC POP at each out-of-pocket price point. We made estimates separately for adult women aged 18–44 and young women aged 15–17.

After reading a description of a POP and OTC access (see supplemental material), respondents were asked how likely they were to buy and use an OTC POP either when it became available or when they needed to change their method of contraception (for users of long-acting reversible contraception). The question specifically asked, "Based on the description of this OTC birth control pill, how likely are you to buy and use it? If you are currently using a long-term method (like the IUD or Implanon/Nexplanon), think about how likely you would be to buy and use this OTC birth control pill the next time you need to change your method." Patients who answered that they were "very likely" or "somewhat likely" to use an OTC POP were considered potential users. Those respondents who said they were likely to use an OTC POP were then asked, "Regardless of your health insurance coverage, what is the highest price (in dollars) that you would be willing and able to pay for each month's supply of this pill [POP] if it were available in a pharmacy or grocery store without a prescription? (If you are not interested in buying pills at any price without a prescription, please type in 0 as your answer.)" Cost was representative of the total out-of-pocket cost the user would incur monthly to purchase the product, regardless of health insurance coverage. We assumed respondents would continue use until their named price. We used the weighted proportion of respondents who reported likely use at each \$1 price point to estimate the probability that a given woman would use an OTC POP; however, we display results in multiples of \$5 given the majority of respondents named prices divisible by \$5. We assumed prices over \$100 were data entry errors ( $n = 1$ ). For any participant who did not name a price ( $n = 15$ ), we assumed the respondent would not pay over \$0. We dropped all survey participants who reported breastfeeding as a method of contraception ( $n = 30$ ) as we could not determine the length of time since last giving birth or whether the respondent was exclusively breastfeeding.

Respondents who reported they were likely to use an OTC POP were also asked, "In what way(s) do you think you might use this OTC birth control pill?" Potential options included: (1) "For short-term use when I run out of pills and can't get a refill quickly," (2) "For short-term use if I have a problem with my current birth control and before I get onto another method," (3) "For short-term use when I start a new relationship before I get onto long-term birth control," (4) "If I didn't have problems with it, I would be interested in staying on it long-term," and (5) "Some other way." Those who answered "If I didn't have problems with it, I would be interested in staying on it long-term" were considered potential long-term users of the method. We explored analyses among long-term users in addition to all potential users of an OTC POP.

We also estimated the probability that an adult woman would use an OTC POP by their most effective current contraceptive method as defined by typical-use failure rates as listed in Table 1 to be able to estimate the number of current and projected number of unintended pregnancies. We assumed that above the

**Table 1**  
Annual Typical-Use Failure Rates for Contraceptive Methods\*

Method	Typical-Use Failure Rate (%)	Notes
Intrauterine device	0.40	Weighted average of levonorgestrel and copper-T based on prevalence of use in 2013–2015 (26% copper-bearing, 74% hormonal) ( <a href="#">National Center for Health Statistics, 2016</a> ).
Implant	0.05	
Injectable (shot)	6.00	
Oral contraceptive <sup>†</sup>	9.00	
Patch	9.00	
Ring	9.00	
Diaphragm	12.00	
Condom	18.00	We used the failure rate for male condoms, as condom type is not specified in the POP interest survey and given the small proportion of female condoms users (<1%) ( <a href="#">National Center for Health Statistics, 2016</a> ).
Withdrawal	22.00	
Fertility-based methods (rhythm)	24.00	
No method ( <a href="#">Vaughan et al., 2008</a> )	46.00	
Exclusive breastfeeding ( <a href="#">Jackson &amp; Glasier, 2011</a> )	2.00	Up to 6 months postpartum

Abbreviation: POP, progestin-only oral contraceptive pill.

\* Typical-use failure rates represent the percent of women that would get pregnant in 1 year using the given contraceptive method as an “average” user. Typical-use failure rates were extracted from [Trussell \(2011\)](#) where not explicitly noted.

<sup>†</sup> Typical-use failure rates are estimated using the National Survey of Family Growth. This survey does not ask for brand of pill; thus, combined and progestin-only pills cannot be distinguished. However, because the use of the combined pill is far more common than the use of the progestin-only pill, the results from the National Survey of Family Growth overwhelmingly reflect typical use of combined pills ([Trussell, 2011](#)).

price point named, users would continue using their current contraceptive method and at or below the price point named, they would switch to an OTC POP from their current method.

We conducted a sensitivity analysis, calculating probabilities of use assuming only those who answered they were “very likely” to use an OTC POP would be users (see supplementary material).

To test whether willingness-to-pay for an OTC POP differed systematically by demographic characteristics, we conducted a discrete survival analysis with adults and teens separately. We fit a discrete-time proportional hazards model on the willingness-to-pay data among all likely users of an OTC POP, where price took the place of time and survival was defined as paying the given price. We analyzed whether respondents were willing to pay up to the median price named by survey participants (\$15 for adults and \$10 for teens) ([Grindlay & Grossman, 2018](#)). Participants were considered to have “survived” at each price (in increments of one) up until the price exceed the price point named. We first conducted bivariate analyses of sociodemographic characteristics, including an indicator for each price up to the median. Variables tested included age, education level, race/ethnicity, marital status, language survey was completed in (English or Spanish), whether the participant had ever given birth, region of residence within the United States, poverty level, health insurance status, current birth control use, ever use of an oral contraceptive, ever use of a POP, attempt to get a prescription for hormonal birth control in the past year, and ever had sex with a man (teens only). We then constructed a multivariable model including characteristics that had an estimated F statistic  $\leq 0.05$  in an adjusted Wald test in our bivariate analyses.

#### Total U.S. users of an OTC progestin-only pill

We estimated the total number of OTC POP users and the total number of potential long-term users at a given point in the United States. Using the probability of use at each price point estimated from the POP interest survey by age (teens and adults), we calculated an estimate of the total number of potential US users of an OTC POP. We used the 2015 US Census for US population estimates for women aged 15–17 and 18–44 ([U.S. Census](#)

[Bureau, Population Division, 2017](#)) and the 2013–2015 National Survey of Family Growth ([National Center for Health Statistics, 2016](#)) to estimate the total population of U.S. women meeting the definition of at risk of unintended pregnancy, using the criteria detailed for the POP interest survey. We applied our estimated probability of use of an OTC POP to these populations. Estimates of potential adult users were among sexually active adults while estimates of potential teen users were among teens aged 15 to 17 who were not currently pregnant or trying to get pregnant (regardless of sexual activity).

#### Unintended pregnancies

Using the probability of long-term use of an OTC POP by most effective current contraceptive method estimated above at different out-of-pocket costs, along with typical-use failure rates of contraceptive methods ([Table 1](#)), we estimated the probability that a given adult woman would experience an unintended pregnancy in 1 year. We used a lower estimate of an annual typical-use failure rate among women not using contraception ([Vaughan, Trussell, Kost, Singh, & Jones, 2008](#)) to make a conservative estimate. We used a higher typical-use failure rate among those not using a method of contraception in a sensitivity analysis displayed in the supplemental material. We assumed all interested users switched to using a POP before the year in which this analysis considers and continued use through the end of the year to apply 1-year typical-use failure rates. We extrapolated this to the U.S. female population aged 18 to 44 at risk of unintended pregnancy using the inclusion criteria above, although we also excluded women who were not sexually active in the past 3 months ([Foster et al., 2015](#)) and women who gave birth in the past month, assuming women were anovulatory for the first 4 weeks postpartum ([Jackson & Glasier, 2011](#)). We assumed women up to 6 months postpartum who exclusively breastfed experienced contraceptive benefits. We applied prior estimates of the proportion of women exclusively breastfeeding at 6 months postpartum to the population ([Jackson & Glasier, 2011](#)). Women who were not exclusively breastfeeding beyond 1 month postpartum were assumed to have the same method mix as the larger population aged 18 to 44.

**Table 2**  
Scenarios of Typical-Use Effectiveness of an Over-the-Counter Progestin-Only Pill

Scenarios	One-Year Typical-Use Failure Rate (%)	Assumptions
Scenario 1: Equal typical-use failure rate between prescription and over-the-counter setting	9.0	Assuming no change in behavior that would affect typical-use effectiveness.
Scenario 2: Decrease in typical-use failure rate in over-the-counter setting	4.5	Assuming continuation of use would be improved in an over-the-counter environment, as was observed in one study. (Potter et al., 2011)
Scenario 3: Increase in typical-use failure rate in over-the-counter setting	13.5	Assuming worse adherence among over-the-counter users.

To calculate the change in unintended pregnancies resulting from OTC POP use, the estimated number of unintended pregnancies at each price of an OTC POP was subtracted from the estimated number of unintended pregnancies calculated using the current method mix. Teens were excluded given the small number of sexually active teens in the POP interest survey.

We constructed three scenarios for typical-use effectiveness for an OTC POP (Table 2), in which effectiveness was the same, higher, and lower than typical-use effectiveness for a prescription OC, modeled after Foster et al. (2015).

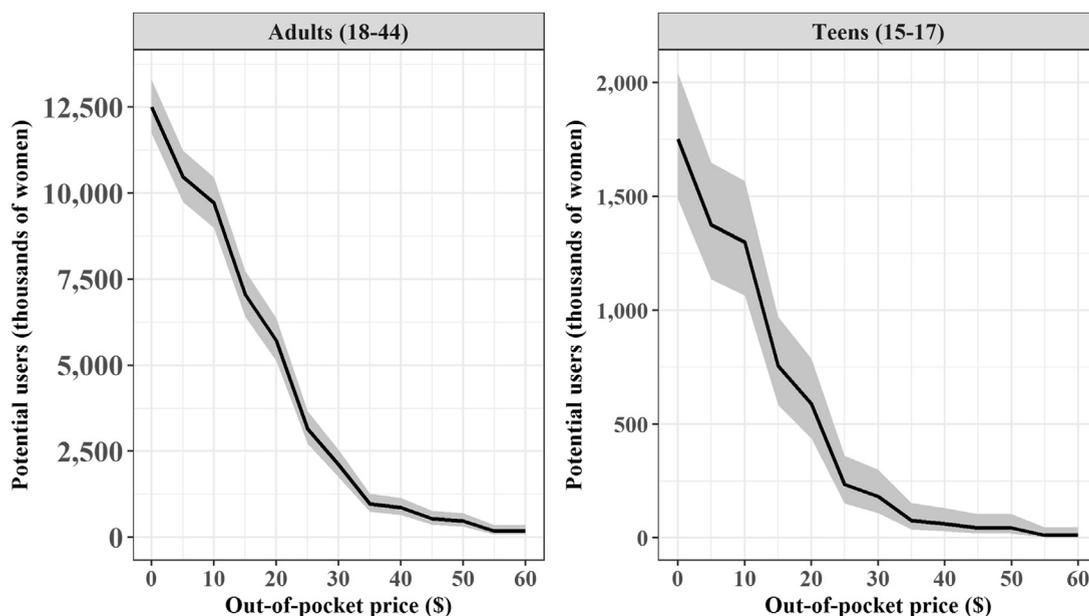
A 95% confidence interval (CI) was generated for all estimates by bootstrapping the observed data 1,000 times using Rao and Wu's rescaled bootstrap implemented using bootstrap replication weights (Rao & Wu, 1988; Wu, Rao, & Yue, 1992).

All analyses accounted for the POP interest survey design using the svy command in Stata and survey package in R (Lumley, 2004). Analyses were conducted using Stata 14 SE (Stata Corp., College Station, TX) and R statistical software (R Core Team, Vienna, Austria).

The study was approved by the Allendale Investigational Review Board.

## Results

Sample characteristics have been described elsewhere (Grindlay & Grossman, 2018). In the population of adults at risk of unintended pregnancy, 38.5% (95% CI, 36.1%–40.9%), or 12.5 million adult women at risk of unintended pregnancy (95% CI, 11.7–13.3 million), were interested in using an OTC POP at no out-of-pocket cost (Figure 1). The population of potential users dropped as the out-of-pocket price increased. Seventy-eight percent (95% CI, 74.8%–81.5%), or 7.0 million (95% CI, 6.3–7.7 million), of the adult users at no out-of-pocket cost would be willing to pay \$10. At the median price adult women were willing to pay, \$15, only 56.9% (95% CI, 52.9%–60.8%) or 7.1 million (95% CI, 6.4 million–7.7 million) of those users interested at \$0 out-of-pocket would use the product. In our sensitivity analysis assuming only those who said they were very likely to use an OTC POP would become users, we estimated 4.4 million users among adult women (95% CI, 3.9 million–5.0 million) at no out-of-pocket cost (Figure S1). At \$15, the number of users in the sensitivity analysis decreased to 2.7 million (95% CI, 2.3 million–3.1 million). When estimating long term users, 25.9% (95% CI,



**Figure 1.** Number of potential users of an over-the-counter progestin-only pill in the United States among adult and teen women at risk of unintended pregnancy. For adult women, we include those at risk of unintended pregnancy, defined as women who are not currently pregnant or trying to get pregnant, women who are not sterilized or whose partners are not sterilized, and women who have had sex with a man in the past 12 months. For teens, we include teens who are not pregnant or trying to become pregnant. The grey ribbon represents the 95% confidence interval for the number of estimated users. The mean estimate is displayed in black.

23.8%–28.1%), or 8.4 million adult women at risk of unintended pregnancy (95% CI, 7.7 million–9.1 million), were interested in using an OTC POP long term at no out-of-pocket cost.

Among teens, more than 1.75 million young women aged 15 to 17 (95% CI, 1.5 million–2.0 million) would use the pill at no out-of-pocket cost, translating to 28.9% (95% CI, 24.5%–33.7%) of this population. At \$10, 76.2% (95% CI, 67.1%–83.4%) or 1.3 million (95% CI, 1.1 million–1.6 million) of the original teen users at no out-of-pocket cost would use the product, and at \$15, only 12.5% of all young women (95% CI, 9.6%–16.0%) or 760,000 (95% CI, 580,000–970,000) aged 15 to 17 were willing to pay. In our sensitivity analysis assuming only those who answered they were very likely to use an OTC POP would become users, 615,000 teens (95% CI, 448,000–835,000) would use an OTC POP at \$0 out-of-pocket cost. At \$10, there were 520,000 teens (95% CI, 370,000–730,000) who would be very likely to use an OTC POP. Among those who identified as long term users, 1.3 million young women aged 15 to 17 (95% CI, 1.1 million–1.6 million) would be likely users at no out-of-pocket cost.

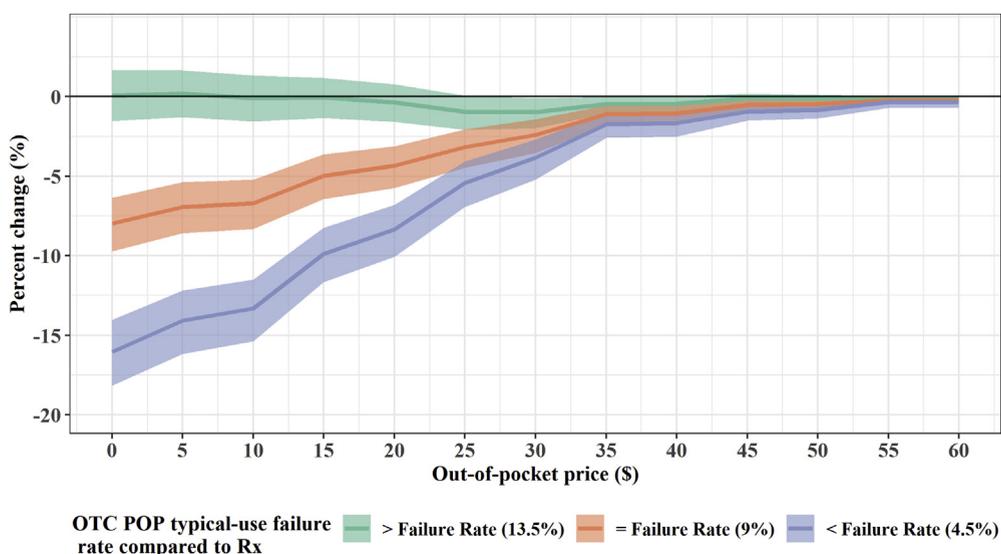
At more than \$20, only 10% of adults (95% CI, 8.5%–11.4%) and 3.9% of teens (95% CI, 2.5%–6.0%) were willing to pay for an OTC POP.

When all long-term users of an OTC POP were able to obtain the method at no out-of-pocket cost, the rate of unintended pregnancies decreased by 8.0% (95% CI, 6.4%–9.7%) assuming a 9% typical-use failure rate in an OTC setting among adults at risk of unintended pregnancy. With a typical-use failure rate of 4.5%, the rate of unintended pregnancies decreased by 16.0% (95% CI, 14.0%–18.2%) at no out-of-pocket cost. With a typical-use failure rate of 13.5%, we predicted no change in unintended pregnancies from current levels (0.6%; 95% CI, –1.5% to 1.7%) (Figure 2). Assuming equal typical-use failure rate between a prescription and OTC POP, the rate of unintended pregnancy decreased by more than 5% up to \$15. The biggest decreases in unintended pregnancies were observed among current condom users and women currently using no method of contraception (Figure 3). At \$15, we estimated more than 75,000 averted unintended

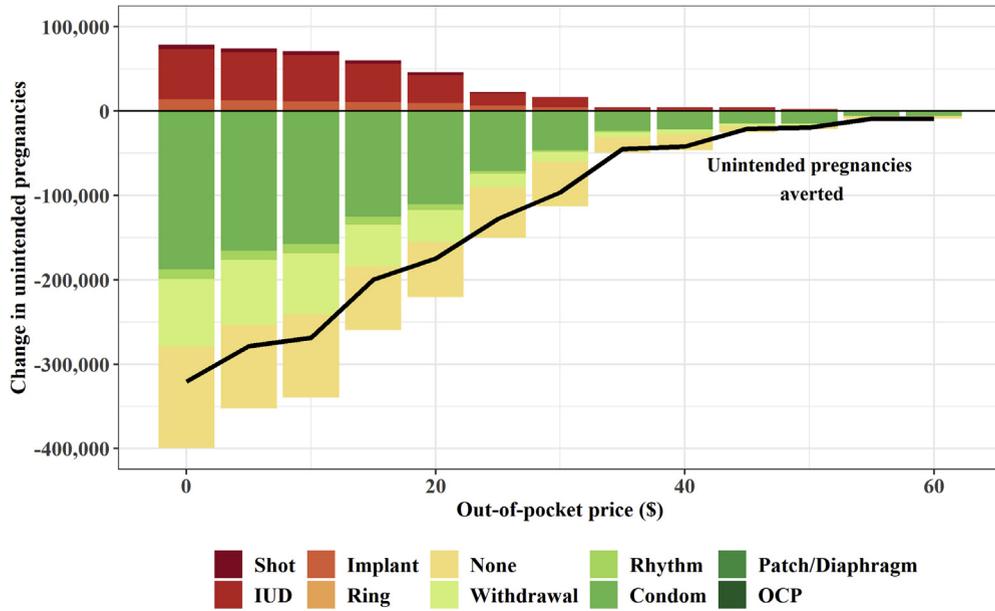
pregnancies (95% CI, 36,200–119,300) among women using no method of contraception, 124,000 averted unintended pregnancies (95% CI, 97,500–152,300) among women currently using condoms, and approximately 199,400 prevented unintended pregnancies overall (95% CI, 143,200–260,000) (Table 3). Assuming all interested IUD users would switch to an OTC method, we estimated an increase of 59,500 (95% CI, 43,600–77,700) unintended pregnancies at no out-of-pocket cost among current IUD users.

In our sensitivity analysis assuming only those who responded they were very likely to use an OTC POP would adopt use of the method, we observed a significant decrease in unintended pregnancy with 9.0% and 4.5% typical-use failure rates (Figure S2). No change was predicted with a 13.5% typical-use failure rate. Assuming a higher typical-use failure rate (85%) among those not using a contraceptive method, we observed a 2.5% (95% CI, 0.4%–4.7%) decrease in unintended pregnancies with a 13.5% typical-use failure rate at no out-of-pocket cost (Figure S3).

Our final multivariable analysis testing differences in willingness to pay among adults included current marital status, current most effective contraceptive method (none, oral contraceptives, other hormonal method or intrauterine device, or a less effective method), current household socioeconomic status (measured as an indicator of whether the household income was less than or equal to 200% of the federal poverty guidelines [FPG]), and an indicator of whether the respondent had sought a prescription or refill of birth control pills, the patch, or the ring in the last year. We found adult users with incomes of more than 200% of the FPG were significantly more likely to pay up to \$15 out-of-pocket for an OTC POP than those with an income of 200% or less of the FPG. At \$10, 81.7% of those interested at no out-of-pocket cost with incomes more than 200% of the FPG were willing to use an OTC POP, compared with 70.6% of those with incomes of 200% or less of the FPG (Figure 4A). Additionally, current oral contraceptive users were less likely to pay any amount up to \$15 than users of other hormonal methods or



**Figure 2.** Estimated percent change in unintended pregnancy among adult women (ages 18–44) at risk of unintended pregnancy. Estimated mean percent change and associated 95% confidence interval in unintended pregnancies in a year among adult women aged 18 to 44 at risk of unintended pregnancy. Each line assumes a different typical-use failure rate for an over-the-counter (OTC) progestin-only pill (POP) compared with the typical-use failure rate in a prescription setting. Results are based on the estimated relationship between out-of-pocket price and purchase.



**Figure 3.** Estimated change in unintended pregnancies in 1 year by most-effective current contraceptive method among adults (ages 18–44) at risk of unintended pregnancy with the introduction of an over-the-counter progestin-only oral contraceptive. Mean change in unintended pregnancies assuming a constant typical-use failure rate between prescription and an over-the-counter progestin-only pill (9%) by most effective current contraceptive method. The bolded line represents the number of unintended pregnancies that would be averted in the population of adult women aged 18 to 44 at risk of unintended pregnancy in a year with the introduction of an over-the-counter progestin-only pill. Results are based on the estimated relationship between out-of-pocket price and purchase. IUD, intrauterine device; OCP, oral contraceptive pill.

intrauterine device users. Widowed, divorced, and separated women were more likely to pay up to \$15 out-of-pocket than their married counterparts (Figure S4). Among teens, only the indicator measuring household income was significant. Therefore, we did not construct a multivariate model among teens. At \$10, 83.9% of potential teen users at no out-of-pocket cost with incomes of more than 200% of the FPG would pay for an OTC POP, compared with 54.8% of teens with household incomes 200% or less of the FPG (Figure 4B).

**Discussion**

This study showed a large population of potential users of an OTC POP translating to potential decreases of 0% to 16% in unintended pregnancies, accounting for different method failure

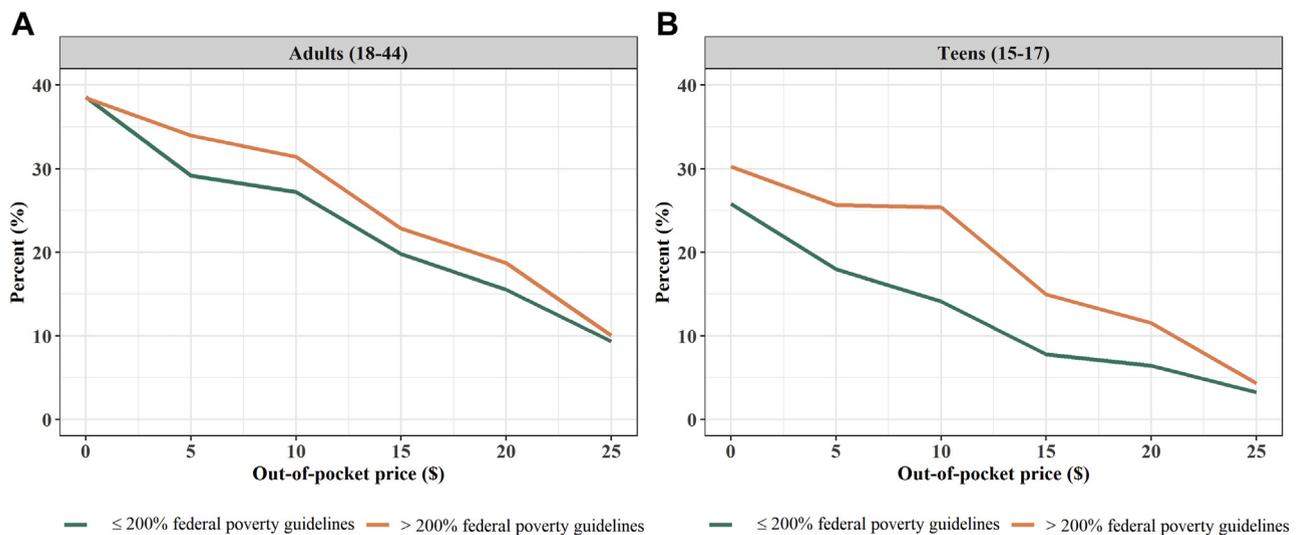
rate scenarios, although willingness to pay differed by socio-economic status. At \$10 out-of-pocket cost, more than 6.9 million adult women at risk of unintended pregnancy and almost 1.1 million teens would potentially use an OTC POP. At more than \$10, the number of potential users decreases to less than 60% of adults and 50% of teens originally interested in using the product. Results indicate that sensitivity to out-of-pocket price for an OTC POP may be greater than for an OTC COC among low-income women (Foster et al., 2015). These results highlight that for an OTC POP to be accessible to low-income women, special consideration must be paid to making this method affordable.

Although we tested different hypothetical scenarios under which the typical-use failure rate of an OTC POP may vary from a prescription setting, there is no strong evidence suggesting that the typical-use failure rate would increase among OTC users. In

**Table 3** Interest in Use of an OTC POP and Estimated Change in Unintended Pregnancies among Adults at Risk of Unintended Pregnancy (Ages 18–44), by Current Most Effective Method of Contraception

Method	N	Using Method (%)	Interested in Any OTC POP Use (\$0) (%)	Interested in Using OTC POP Long Term (\$0) (%)	Change in Unintended Pregnancies at \$0 OOP Cost (9% Failure)	Change in Unintended Pregnancies at \$10 OOP Cost (9% Failure)	Change in Unintended Pregnancies at \$15 OOP cost (9% Failure)
No method	176	9.3	22.9	12.6	-119,839	-98,978	-75,400
Rhythm	27	1.2	26.5	23.7	-11,395	-11,395	-9,120
Withdrawal	184	9.5	30.0	23.4	-80,160	-72,167	-49,807
Condom	457	23.4	42.4	31.8	-186,231	-155,942	-124,174
Diaphragm	9	0.4	41.5	41.5	-1,456	-1,456	-1,087
Patch	10	0.5	42.9	35.0	0	0	0
OCP	673	32.7	52.1	31.8	0	0	0
Ring	40	1.9	15.4	14.8	0	0	0
Shot	81	5.1	21.2	11.9	5,030	4,566	4,248
IUD	273	13.4	29.1	18.4	59,483	54,875	45,214
Implant	58	2.7	28.3	20.7	14,015	11,591	10,727
Total	1,988	100	38.5	25.9	-320,552	-268,907	-199,400

Abbreviations: IUD, intrauterine device; OCP, oral contraceptive pill; OOP, out of pocket; OTC, over the counter; POP, progestin-only oral contraceptive pill.



**Figure 4.** Percent of adults ages 18 to 44 (A) and teens ages 15 to 17 (B) who would use an over-the-counter progestin-only pill, by socioeconomic status. Percent of people in each socioeconomic category who expressed interest in using an over-the-counter progestin-only pill at each price point.

fact, in El Paso, Texas, oral contraceptive users who obtained an oral contraceptive OTC were more likely to continue use than prescription users (Potter et al., 2011). This finding may partly be explained by the number of packs dispensed at one time, a benefit of OTC use. Between OTC and prescription users in El Paso, authors found similar proportions of women discontinuing oral contraceptive use because they reported getting pregnant while using the method (approximately 15%) (Potter et al., 2011). In a scenario where the typical-use failure rate stays constant or even increases slightly between the prescription setting and the OTC setting, the availability of an OTC POP has the potential to decrease the number of unintended pregnancies at the population level, although increases are seen among current users of methods that are more effective than oral contraceptives. Keeping out-of-pocket costs low would have the largest potential impact on the rate of unintended pregnancies; consistent with the findings from previous studies (Foster et al., 2015).

Even if no decrease is observed in the unintended pregnancy rate when a POP does become available OTC, OTC access to an oral contraceptives brings broader benefits—addressing barriers in obtaining and paying for an appointment with a doctor or clinician and preventing gaps in use (Frost, Singh, & Finer, 2007; Grindlay & Grossman, 2016). An OTC POP will be the most effective OTC contraceptive available. An OTC POP will provide an option to those who currently lack access to more effective methods of contraception, and offer an effective interim alternative for those in the process of switching between contraceptive methods.

Our analysis shows that affordability and insurance coverage for an OTC POP are key to ensuring that populations, especially low-income people, who may lack access to more effective methods and would prefer to switch, are able to afford and access the product. Several states, including Illinois (Nekritz, Wallace, & Tabares, 2016), Maryland (Kelly, 2016), and Oregon (Barker, Williamson, & Fahey, 2017), have passed legislation ensuring coverage for OTC methods. Such legislation at the state and national level is crucial to making this future product accessible. However, legislation that ensures insurance coverage for OTC contraceptives only helps those with health insurance;

efforts to keep retail prices low ensure those without insurance can access an OTC POP. Out-of-pocket costs of more than \$10 could price out those without insurance coverage, especially considering the median out-of-pocket expenditure for contraception in 2015 was \$0 (Grindlay & Grossman, 2018).

This study has several limitations. First, we cannot test the assumptions used in this analysis given that there is no current oral contraceptive available OTC; however, we have generated a number of sensitivity analyses to show a range of potential scenarios. Additionally, the population of potential users of teens and adults is not directly comparable given the inclusion criteria. The estimate of potential users for adults may be an underestimate given it does not include potential users who were not sexually active in the past year, while the estimate of teen users is based on a broader population, including teens who are not sexually active. We used a conservative estimate of the proportion of women using no method of contraception that would become pregnant in a year. Thus, we likely underestimated the potential number of averted unintended pregnancies. However, we considered all method failures unintended pregnancies, ignoring the complexity of potential feelings around a pregnancy. Our hypothetical scenario assumes that all potential users would use the method in the same year and we did not account for discontinuation or uptake of other methods. Additionally, no data exist that parse apart the typical-use failure rates of POPs from COCs. The typical-use failure rate presented for prescription oral contraceptives most likely reflects the typical-use failure rate of COCs, as they are more commonly used in the United States. Although it is widely thought that POPs are less effective than COCs, there is little evidence to support this claim (Grimes, Lopez, O'Brien, & Raymond, 2010).

### Implications for Practice and/or Policy

A large population of women at risk of intended pregnancy are likely to use a progestin-only pill should it become available OTC. Depending on use patterns and the typical-use failure rate, an OTC POP has the potential to decrease unintended pregnancy. Policymakers should work to pass laws requiring insurance to

cover OTC contraceptives and advocates and decision makers should urge pharmaceutical companies to sell an OTC POP at a price affordable to those with a range of incomes.

## Conclusions

At low and no out-of-pocket cost, a large population of women in the US might likely use an OTC POP. A low retail price and insurance coverage are necessary to provide equitable access to this method for low-income populations across the United States and to fill current gaps in contraceptive access.

## Acknowledgments

Supported by The David and Lucile Packard Foundation [Grant number 2015-63012] and The William and Flora Hewlett Foundation [grant numbers 2012-7908, 2015-2997]. The funders had no involvement with the study design; collection, analysis, and interpretation of the data; writing of the manuscript; or the decision to submit the manuscript for publication.

Ibis Reproductive Health has a formal partnership with HRA Pharma to work together on the research needed for an application to the United States Food and Drug Administration to make a birth control pill available over the counter (OTC). Ibis does not receive financial support from HRA Pharma and has no financial interest in an OTC product. Ibis has taken a public stand on the need for insurance coverage of OTC contraceptives, including an OTC oral contraceptive. Grindlay, Grossman, and Wollum have no further conflicts of interest to disclose. Although Trussell reviewed a close to final manuscript, he passed away in December 2018 and we have not been able to confirm his statement of disclosure.

We would like to thank Germán Rodríguez, PhD, of Princeton University for the input he provided on the methods used in this study. AW and KGK had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. James Trussell was supported in part by an infrastructure grant for population research from the Eunice Kennedy Shriver National Institute of Child Health and Development, National Institutes of Health, United States P2C HD047879.

## Supplementary Data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.whi.2020.01.003>.

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