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Original Research Article

Modeling the potential benefit of an over-the-counter progestin-only pill in preventing unintended pregnancies in the U.S. ☆,☆☆

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ABSTRACT

Objectives: To develop a model to estimate the possible impact of use of an over-the-counter (OTC) progestin-only pill (POP) on the number of unintended pregnancies in the United States.
Study design: Using typical use failure rates (7% for POPs), we compared the expected number of unintended pregnancies for two theoretical cohorts of 100,000 women: one which purchased and used an OTC POP exclusively for contraception, the other using contraceptive methods at proportions obtained from an actual-use clinical trial simulating OTC use of norgestrel 0.075 mg (including 35% using no method and only 19% using hormonal contraception or long-acting contraceptives). Sensitivity analyses were conducted using alternative model inputs such as different failure rates for OTC POPs and varied alternative contraceptive method mix.
Results: An estimated 37,624 unintended pregnancies would occur annually if 100,000 women continued their usual contraceptive method as used at baseline in the actual use trial. This would be reduced by 81% to 7,000 pregnancies with the exclusive use of an OTC POP – a net reduction of 30,624 unintended pregnancies annually. While the number of unintended pregnancies prevented varied as the model parameters were modified (ranging from 1,461 to 34,124), a net benefit of OTC POP use was observed over a wide range of input values.
Conclusions: Using data from a real-world contraception user profile, our model suggests that use of an OTC POP could reduce the overall number of unintended pregnancies in the United States. This conclusion remains true across a wide range of modeled scenarios.
Implications: The estimates suggested by this model are supportive of an OTC switch for a POP.

1. Introduction

Unintended pregnancy is a major public health issue in the United States, where almost half of the 6.1 million annual pregnancies are unintended [1–3]. Contraception prevents unintended pregnancies, but barriers to accessing contraception, including the prescription requirement for oral contraception, contribute to inconsistent use or nonuse [4]. Major medical organizations have expressed strong support for having effective contraceptives, such as progestin-only pills (POPs), available over-the-counter (OTC) [4,5]. While OTC availability of a method of contraception that is more effective than those presently available without a prescription (mostly condoms and spermicides) should prevent unintended pregnancies in individual women, the potential effect at a population level is unknown.

Wollum et al. [6] modeled the potential impact of having a POP in the OTC setting. From a nationally representative cross-sectional survey [7] conducted in 2015 and using data from 2,026 US women aged 18 to 44 who expressed an interest in using a POP if it were

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Table 1
Distribution of contraceptive methods used prior to enrolling in the OTC simulated actual-use clinical trial (US, 2022)

	Ages 11–17 *N* = 200 *N* (% total, % subgroup)[a]	Ages 18–24 *N* = 271 *N* (% total, % subgroup)	Ages 25–34 *N* = 259 *N* (% total, % subgroup)	Ages 35+ *N* = 153 *N* (% total, % subgroup)	Total *N* = 883 *N* (% total)
No method	120 (14%, 60%)	75 (8%, 28%)	72 (8%, 28%)	45 (5%, 29%)	312 (35%)
Spermicides / female condom	0 (0%, 0%)	0 (0%, 0%)	1 (0%, 0%)	0 (0%, 0%)	1 (0%)
Withdrawal	3 (0%, 2%)	21 (2%, 8%)	16 (2%, 6%)	8 (1%, 5%)	48 (5%)
Diaphragm / sponge	0 (0%, 0%)	0 (0%, 0%)	0 (0%, 0%)	0 (0%, 0%)	0 (0%)
Natural FP / rhythm method	0 (0%, 0%)	9 (1%, 3%)	10 (1%, 4%)	7 (1%, 5%)	26 (3%)
Male condom	48 (5%, 24%)	105 (12%, 39%)	104 (12 %, 40%)	69 (8%, 45%)	326 (37%)
COC / POP / patch / vaginal ring	23 (3%, 12%)	51 (6%, 19%)	54 (6%, 21%)	24 (3%, 16%)	152 (17%)
Injectable	3 (0%, 2%)	4 (0%, 1%)	0 (0%, 0%)	0 (0%, 0%)	7 (1%)
LARC	3 (0%, 2%)	6 (1%, 2%)	2 (0%, 1%)	0 (0%, 0%)	11 (1%)

COC, combined oral contraceptive; FP, family planning; LARC, Long-acting reversible contraceptive; *N*, number of subjects; POP, progestin-only pill.
[a] % Total and % Subgroup refer to percent of women out of the total sample of 883, and percent of women among the age group, respectively.

available OTC [8], they estimated that an OTC POP would reduce the number of unintended pregnancies by 8% (around 199,400 pregnancies/year in the United States) [6]. The impact of OTC POP availability clearly depends on the preceding contraceptive practices of the women who switch to the OTC POP: women switching from a more effective contraceptive to a POP would be theoretically more likely to have an unintended pregnancy while those switching from a less effective method, or from no method, would have a lower risk. The Wollum model used data from women expressing interest in an OTC POP [8], but the value for women who might actually purchase a POP OTC and use it has not been estimated.

A recent actual-use clinical trial simulating the OTC use of a POP, norgestrel 0.075 mg, over a 6-month period [9] provides important data on the distribution of different contraceptive methods among potential OTC POP users. The objective of our model is to utilize data on the baseline distribution of different contraceptive methods from the actual-use trial [9] to draw conclusions on the potential impact of the use of a POP when available OTC on the number of unintended pregnancies in the United States.

2. Material and methods

We obtained data from a recent actual-use clinical trial which simulated OTC use of a norgestrel 0.075 mg POP over a 6-month period (NCT04112095) [9]. In this trial, 883 women chose to pay out-of-pocket and use the norgestrel POP. The study staff collected baseline demographic characteristics (Table A.1) of the participants and the methods of contraception used before enrollment (Table 1) (a summary of the actual-use trial methods is provided in Appendix 2).

To produce the model outputs, we normalized estimates to a population of 100,000 women. We compared the number of pregnancies expected among two hypothetical cohorts of 100,000 women using different contraceptive methods over 1 year. The first cohort was women whose contraceptive method mix was based on that of the volunteers entering the actual-use trial had they continued to use the contraceptive method they reported prior to their enrollment. The second cohort (women choosing to buy and use an OTC POP as their contraceptive method) was women exclusively using an OTC POP (Fig. 1). We used annual typical use failure rates as reported by Trussell, 2018 [10] to estimate resulting pregnancy rates (shown in Table 2).

2.1. Primary analysis

For the primary analysis, we set the failure rate of the OTC POP as 7%, the reported failure rate for oral contraceptive pills [10], and that of "no method" as 85% [10]. For the cohort of women not using an OTC POP, no modifications were made to the proportions of use of each contraceptive method obtained from the actual-use trial at baseline.

2.2. Sensitivity analyses

We tested several scenarios to account for variability and uncertainty inherent to the inputs used in the model. First, we replaced the actual-use trial contraceptive use distribution with the contraceptive distribution reported in the 2017 to 2019 data from the US National Survey of Family Growth (NSFG) [11]. The NSFG cohort included a higher percentage of users of the most effective contraceptive methods and a lower percentage of users of no method.

Additionally, we reduced the 7% failure rate of POPs from Trussell [10] by half to 3.5%, assuming continuation of POP use might be improved in an OTC environment, as observed in one study [12], and we also increased the POP failure rate by half to 10.5%, assuming adherence to POP use might be worse in the OTC setting. For both scenarios of decreased and increased OTC POP failure rate, we also decreased the original 85% "no method" failure rate from Trussell [10] to 46% based on Vaughan [13], to generate a more conservative estimate.

Finally, as teens were deliberately over-recruited in the actual-use trial, we ran an additional sensitivity analysis where we excluded adolescents under age 18, 60% of whom were using no method (Table 1).

2.3. Tipping-point analysis

We conducted a "tipping-point" analysis to determine the failure rate of the OTC POP beyond which no unintended pregnancies would be prevented by OTC POP use compared with the method mix used by the actual-use trial cohort prior to enrollment or the method mix from NSFG. This analysis gradually increased the failure rate of the OTC POP beyond 7% to yield an equal number of unintended pregnancies between the cohort not using the OTC POP and that using the OTC POP. We did this analysis under two scenarios of assuming a "no method" failure rate of 85% [10] and 46% [13].

2.4. Continuation in use analyses

In an additional analysis, we attempted to determine the effect that discontinuation of the OTC POP might have on the estimates of the number of unintended pregnancies prevented. OTC POP continuation rates during 6 months in the OTC actual-use trial are shown in Table 3. We did this analysis over a 6 month use period, since the actual-use trial provided data up to 6 months of OTC POP use. We assumed that the cohort not using the OTC POP used a contraception method mix in proportion to that obtained

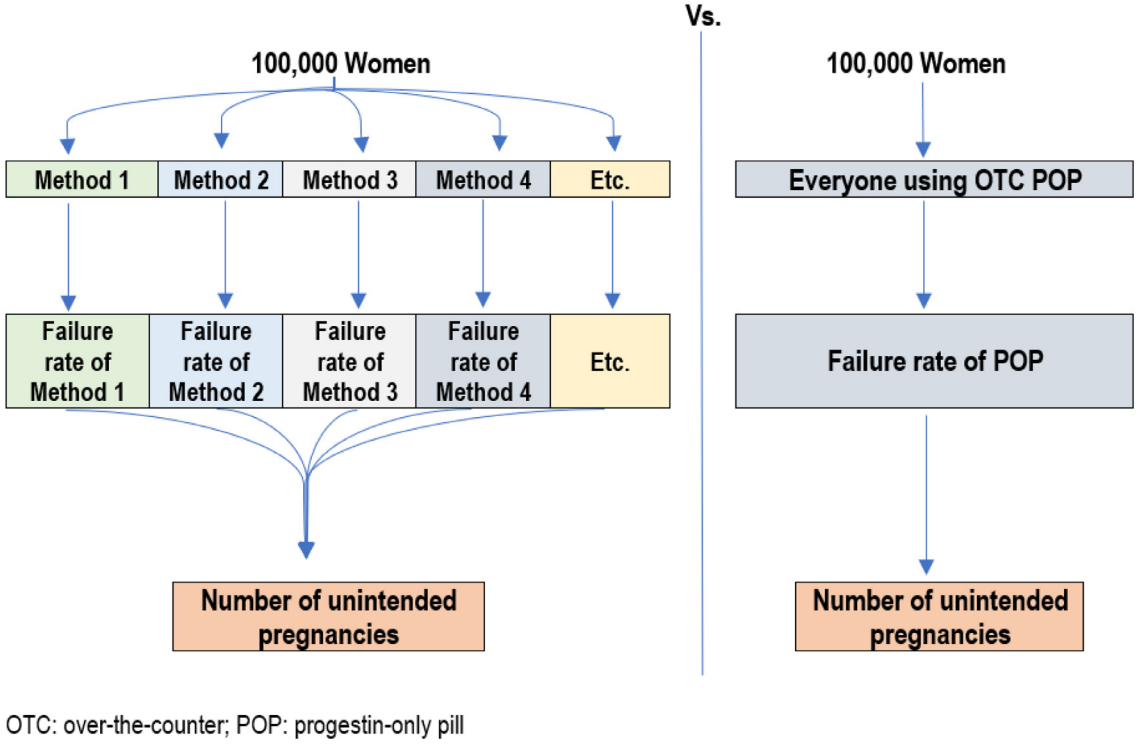

Fig. 1. Model concept; Comparing the estimated number of unintended pregnancies in a hypothetical cohort of 100,000 women if they had no access to OTC POP and continued using currently available methods for 1 year vs if they had access to OTC POP and exclusively used an OTC POP

Table 2
Outcomes of the primary analysis: number and proportion of unintended pregnancies prevented with use of OTC POP instead of methods used when no OTC POP available in a hypothetical cohort of 100,000 women over 1 year (US, 2022)

Methods used when no OTC POP available	Distribution of methods used when no OTC POP available	Method typical use failure rate [10]	Pregnancies expected with methods used when no OTC POP available	Pregnancies expected with use of OTC POP (7% failure rate)	Number (proportion) of pregnancies prevented by use of OTC POP vs when no OTC POP available
No method	35%	85%	30,034	2,473	27,561 (92%)
Spermicides / female condom	0%	21%	24	8	16 (67%)
Withdrawal	5%	20%	1,087	381	707 (65%)
Diaphragm / sponge	0%	17%	0	0	0 (0%)
Natural FP / rhythm method	3%	15%	442	206	236 (53%)
Male condom	37%	13%	4,800	2,584	2,216 (46%)
COC / POP / patch / vaginal ring	17%	7%	1,205	1,205	0 (0%)
Injectable	1%	4%	32	55	-23 (-72%)
LARC	1%	0.1%	1	87	-86 (-6900%)
TOTAL:			37,624	7,000	30,624 (81%)

COC, combined oral contraceptive; FP, family planning; LARC, long-acting reversible contraceptive; OTC, over-the-counter; POP, progestin-only pill.

Table 3
Percentage of continued use of OTC POP per month in the OTC simulated actual-use clinical trial (US, 2022)

Timepoint	Proportion of subjects with continued OTC POP use
Mo 1	100.0%
Mo 2	86.6%
Mo 3	73.5%
Mo 4	64.1%
Mo 5	56.1%
Mo 6	51.1%

OTC, over-the-counter; POP, progestin-only pill.

from either the actual-use trial or NSFG. We assumed that the cohort using the OTC POP exclusively used the POP and discontinued it at the rate in Table 3. We also assumed that when they stopped the OTC POP, they resumed use of the methods the actual-use trial subjects reported using prior to enrollment, or when we used the NSFG method mix profile, we assumed that they switched from OTC POP to a method mix in proportion to that reported in NSFG. We did this analysis using the Trussell [10] typical-use failure rates but also varied the failure rates for the OTC POP (3.5% or 10.5%) and "no method" (46% [13]), each reduced by 50% to yield the expected failures during a 6-month period.

3. Results

3.1. Primary analysis

An estimated 37,624 unintended pregnancies would be expected to occur if 100,000 women continued their current contraceptive method over the course of 1 year when the contraceptive method mix used is that observed at baseline in the OTC actual-use trial and assuming a "no method" failure rate of 85% (Table 2). In contrast, if those 100,000 women used the OTC POP (with a failure rate of 7%) and exclusively used this as their contraception for

Table 4
Outcomes of the primary and sensitivity analyses: number and proportion of unintended pregnancies prevented with use of OTC POP instead of methods used when no OTC POP available, in a hypothetical cohort of 100,000 women over 1 year (US, 2022)

OTC POP failure rate	"No method" failure rate	Pregnancies expected when no OTC POP available		Pregnancies expected with OTC POP used	Number (proportion) of pregnancies prevented by use of OTC POP vs when no OTC POP available	
		using OTC trial method mix profile	using NSFG method mix profile		using OTC trial method mix profile	using NSFG method mix profile
Primary analysis						
7%	85%	37,624	16,992	7,000	30,624 (81%)	9.992 (59%)
Sensitivity analyses						
3.5%	85%	37,624	16,992	3,500	34,124 (91%)	13,492 (79%)
10.5%	85%	37,624	16,992	10,500	27,124 (72%)	6,492 (38%)
7%	46%	23,844	11,961	7,000	16,844 (71%)	4,961 (41%)
3.5%	46%	23,844	11,961	3,500	20,344 (85%)	8,461 (71%)
10.5%	46%	23,844	11,961	10,500	13,344 (56%)	1,461 (12%)

NSFG, National Survey of Family Growth; OTC, over-the-counter; POP, progestin-only pill.

1 year, an estimated 7,000 unintended pregnancies would be expected to occur. Thus, in a cohort of 100,000 women whose contraceptive use profile is based on methods used prior to enrollment by women who then used a POP in a simulated OTC setting, and assuming an OTC POP failure rate of 7% and "no method" failure rate of 85%, an estimated 30,624 unintended pregnancies would be prevented over 1 year by use of an OTC POP. This represents a reduction in unintended pregnancies of over 80%.

3.2. Sensitivity analyses

When the estimate for the OTC POP failure rate was decreased from 7% to 3.5%, an estimated 34,124 unintended pregnancies would be prevented among the 100,000 women by use of an OTC POP for 1 year versus their current contraceptive methods (Table 4). In contrast, when increasing the OTC POP failure rate to 10.5%, reducing the "no method" failure rate to 46%, and using the NSFG contraceptive method mix, an estimated 1,461 unintended pregnancies would be prevented, representing a 12% reduction in unintended pregnancies from the cohort continuing their baseline contraceptive methods (Table 4). When the model was run excluding adolescents under age 18, using a failure rate of OTC POP of 7% and a pregnancy rate among women using no method of 85% after 1 year, the estimated proportion of unintended pregnancies prevented was 78%.

While the effect on the expected number of unintended pregnancies prevented varied as the model parameters were modified, in every scenario we tested, the overall number of expected pregnancies remained lower among the cohort exclusively using an OTC POP (Fig. 2).

3.3. Tipping-point analysis

The tipping point analysis estimated that the typical use failure rate of OTC POPs beyond which there would be no further reduction in unintended pregnancies is 38% when using the OTC actual-use trial method mix profile and the "no method" failure rate at 85%. Using the most conservative model inputs (i.e., NSFG method mix profile and "no method" failure rate of 46%), a 12% OTC POP failure rate would be required to yield no net reduction in unintended pregnancies.

3.4. Continuation of use analysis

Revised estimates incorporating the observed OTC POP continuation rates in the actual-use trial (Table 3) reduced the benefit to a 59% reduction of unintended pregnancies over 6 months using the OTC actual-use trial method mix profile (for 11,009 pregnancies prevented), and to a 42% reduction using the NSFG method mix profile (for 3,592 pregnancies prevented). These estimates are based on an annual 7% OTC POP failure rate and an annual 85% "no method" failure rate (Table 5). When the annual failure rate of the OTC POP input was increased to 10.5% and the annual "no method" failure rate was decreased to 46%, the number of unintended pregnancies prevented by use of an OTC POP for up to 6 months relative to continuing current contraceptive methods was reduced by 40% and 9% (for 4,797 and 525 pregnancies prevented) using the OTC actual-use trial and NSFG method mix profiles, respectively.

4. Discussion

The need to see a clinician to access effective contraceptives is recognized as a barrier for many women [14]. While availability of an oral contraceptive OTC should facilitate access, the impact on unintended pregnancy rates is unknown. Wollum et al. [6] estimated that an OTC POP would reduce the total number of unintended pregnancies in the United States by 8%. However, the Wollum model used a broad survey of women using a range of contraceptive methods not necessarily typical of those who might buy an OTC oral contraceptive. In contrast, our model uses a contraceptive user profile based on an actual-use clinical trial in which women self-selected to purchase and use a POP in an OTC simulated environment [9]. Based on these data, our model estimated the impact for the population who would choose to use a POP when available OTC. Our model estimated a reduction of 30,624 unintended pregnancies per 100,000 women if the OTC POP was available and used for 1 year (Table 2). While the number of unintended pregnancies varied as the input values were varied, the effect of use of an OTC POP remained beneficial for a wide range of modeled scenarios (Table 4; Fig. 2).

The importance of baseline contraceptive use on the magnitude of benefit with OTC POP use is illustrated by contrasting the actual-use trial cohort with the US NSFG cohort. The former was based on women who used a POP in a simulated OTC environment. The result was a cohort in which there was much more use of less effective contraceptive methods or no method, as compared to the profile obtained in the NSFG survey. Data from the simulated OTC trial likely better reflects the pattern of contraceptive switching that may occur in reality. For example, it is unlikely that many women using an implant or intrauterine device would switch to an OTC POP since they would have to see a health professional to discontinue their method. Data from the 1995 US NSFG [13] demonstrated rates of method switching within 2 years of initiation among unmarried women of 70% among non-users compared with 33% among long-acting reversible contraceptive users. This is borne out by data from the OTC actual-use trial in which only 1.2% of women who took an OTC POP were previously using

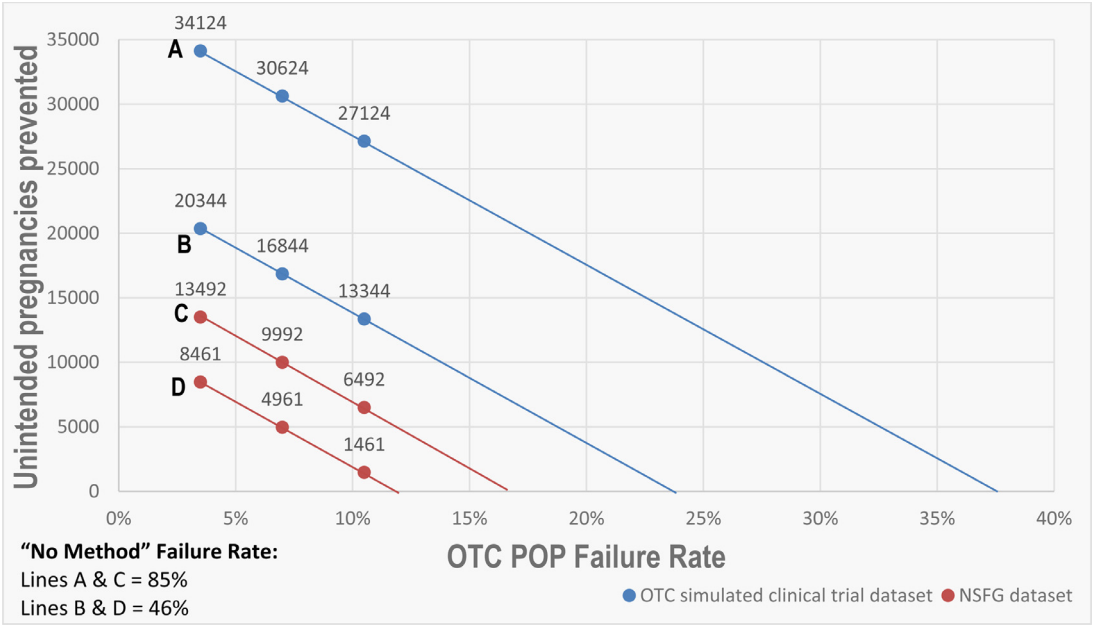

Fig. 2. Number of unintended pregnancies prevented with use of OTC POP instead of methods used when no OTC POP available in a hypothetical cohort of 100,000 women over 1 year, per OTC POP failure rate, and per "no method" failure rate; Figure footnote: This figure displays the number of unintended pregnancies prevented (Y-axis) per OTC POP typical use failure rate (X-axis), when using the contraceptive method mix profile from the OTC actual-use trial (blue points) and NSFG (orange points) datasets, in two scenarios of assuming the "no method" failure rate at 85% (Lines A & C) and 46% (Lines B & D). Each line includes three datapoints, representing the estimated number of prevented unintended pregnancies calculated under the three assumed OTC POP failure rates of 3.5%, 7%, and 10.5%, respectively. The X-intercept of each line represents the failure rate of OTC POP beyond which the number of unintended pregnancies expected when no OTC POP is available equals the number of unintended pregnancies expected when exclusively using OTC POP, i.e., the "tipping point."

Table 5
Outcomes of the continuation of use analysis: number and proportion of unintended pregnancies prevented with use of OTC POP instead of methods used when no OTC POP available in a hypothetical cohort of 100,000 women over 6 months, taking into consideration decline in OTC POP use with time (US, 2022)

		Pregnancies expected when no OTC POP available		Pregnancies expected with OTC POP available		Number (proportion) of pregnancies prevented with OTC POP available	
OTC POP failure rate	"No method" failure rate	using OTC trial method mix profile	using NSFG method mix profile	using OTC trial method mix profile	using NSFG method mix profile	using OTC trial method mix profile	using NSFG method mix profile
7%	85%	18,812	8,496	7,803	4,904	11,009 (59%)	3,592 (42%)
3.5%	85%	18,812	8,496	6,545	4,138	12,267 (65%)	4,358 (51%)
10.5%	85%	18,812	8,496	9,062	6,162	9,750 (52%)	2,334 (27%)
7%	46%	11,922	5,980	5,867	4,197	6,055 (51%)	1,783 (30%)
3.5%	46%	11,922	5,980	4,609	2,939	7,313 (61%)	3,041 (51%)
10.5%	46%	11,922	5,980	7,125	5,455	4,797 (40%)	525 (9%)

NSFG, National Survey of Family Growth; OTC, over-the-counter; POP, progestin-only pill.

a long-acting reversible contraceptive, while 35% were previously using no method and 37% had been using condoms (Table 1). Consistent with the hypothesis that OTC status would facilitate access to effective contraception for women who currently find it difficult to obtain, 90% of the prevented pregnancies in the primary analysis were attributable to sexually active women previously using no contraception initiating an OTC POP. This outcome is consistent with the conclusion of Thomas and Karpilow who showed that the largest effects on fertility outcomes would come from the uptake of any method among sexually active women who neglect to use birth control despite not seeking pregnancy [15].

Consistent with results of Wollum et al. [6], a net benefit was observed over a range of estimates for OTC POP effectiveness. The tipping point analysis further supported a net benefit in the OTC setting unless implausible failure rates were imputed.

As is the case with prescription oral contraceptives [16], discontinuation of OTC POPs will occur. Real-world data from the OTC simulated trial provided estimates of continuation over 6 months. Trussell reports that 67% of women using either POPs or COCs are still using the method at the end of first year of use. A number of studies have suggested that menstrual cycle disturbances are a common cause for POP discontinuation [17]. In the actual-use trial, as expected, fewer women (51%) were still using the POP at the end of 6 months. Continuation was likely lower in the trial versus a real OTC setting as participants had to return to a single study site up to 100 miles from their home to purchase additional drug versus the multiple retail sites that will exist in a real OTC marketplace. Using the most pessimistic failure rate assumptions, when discontinuation rates from the actual-use trial are accounted for, the model estimates, for a total of 6 months overall, prevention of almost 5,000 pregnancies (40%) in the cohort using the actual-use trial method mix and 525 pregnancies (9%) in the NSFG cohort (Table 5).

Thus, any period of effective contraception with the OTC POP will yield a health benefit even if the woman later reverts to her original method.

As with any model, there are important limitations. All model inputs are based on uncertain estimates, albeit based on the best available data. The profile of pre-enrollment methods of contraception in the actual-use trial was self-reported and might not be

accurate and might also not reflect OTC POP users who are not participating in a trial. Thus, no effort has been made to generalize to the overall US population post-approval of an OTC POP. Because we assumed the results may also be influenced by the deliberate over-recruitment of teens into the trial who likely have a differential pregnancy risk versus adults [18], we ran an additional sensitivity analysis where we excluded adolescents under age 18, 60% of whom were using no method (Table 1). However, the estimated proportion of unintended pregnancies prevented in the population excluding adolescents was hardly different from the proportion with adolescents (78% and 81%, respectively).

The sensitivity analyses illustrate the quantitative impact of varied inputs on the resulting estimates, but also make clear the expectation of net benefit over a range of plausible values for the inputs. The actual-use clinical trial lasted only 6 months while contraceptive continuation rates are traditionally reported for 1 year of use. While discontinuation will likely be higher over 1 year, the rate of discontinuation is often highest during the first 6 months of use [19]. Additionally, the model assumed that the women who discontinued the OTC POP returned to using the method they were using when they entered the study, which they may not.

Finally, the Wollum model analyzed women's likelihood of using of an OTC pill at different price points and by sociodemographic characteristics which we did not do [6]. The price of an OTC POP will undoubtedly influence the potential total number of US users and therefore the number of unintended pregnancies prevented.

In conclusion, the model supports the hypothesis that use of a POP when available OTC will result in a clinically meaningful reduction in unintended pregnancies in the United States. This reduction will yield important progress on national public health goals [3] while yielding personal health benefits to women currently using less effective or no contraceptive methods.

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We would like to thank all the participants who used the norgestrel POP in simulated OTC conditions in the actual-use clinical trial used in the model, contributing to our collective understanding of what contraceptive methods potential users of an OTC POP might switch from, and for how long they might use such a method if available OTC. We also thank all of those at PEGUS Research, Ibis Reproductive Health, Pinney Associates and HRA Pharma who contributed to the development of this model and this manuscript. We also thank all those at Smart Analyst who contributed to the initial critical thinking to develop such a model.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.contraception.2022.10.006.

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