Original research article

Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users

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Abstract

Background: Interest is growing in moving oral contraceptives over-the-counter (OTC), although concerns exist about whether women would continue to get preventive health screening.

Study Design: We recruited cohorts of US-resident women who obtained oral contraceptives from US family planning clinics (*n*=532) and OTC from pharmacies in Mexico (*n*=514) and interviewed them four times over 9 months. Based on self-reports of having a Pap smear within 3 years or ever having had a pelvic exam, clinical breast exam and testing for sexually transmitted infections (STIs), we assessed the prevalence of preventive screening using Poisson regression models.

Results: The prevalence of screening was high for both groups (>88% for Pap smear, pelvic exam and clinical breast exam and >71% for STI screening), while the prevalence ratios for screening were higher for clinic users, even after multivariable adjustment.

Conclusions: Results suggest that most women would obtain reproductive health preventive screening if oral contraceptives were available OTC, and also highlight the need to improve access to preventive screening for all low-income women.

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Keywords: Over-the-counter oral contraceptives; Preventive screening; Pap smear; Clinical breast exam, STI screening

1. Introduction

A growing body of evidence suggests that over-the-counter (OTC) access to oral contraceptives (OCs) is safe and effective, and this provision model may be preferable to some women [1]. A national telephone survey in 2004 found that 68% of women would obtain OCs, the patch or vaginal ring at a pharmacy if they were available without a prescription, and 41% of nonusers said they would start one of these methods [2]. US-resident women obtaining OCs OTC in Mexican pharmacies were found to have improved continuation compared to those who obtained OCs in US clinics [3]. Several studies have found that women can accurately self-screen for contraindications to combined oral contraceptives (COCs) using simple checklists [4,5]. How-

ever, a recent study found that US women who obtained COCs OTC in Mexican pharmacies were more likely to have a contraindication to COCs than those obtaining OCs in US clinics, suggesting that a progestin-only pill (POP) might be the best option for the first OTC OC in the USA [6].

One concern that has been voiced about making OCs available OTC is that women would not obtain recommended preventive screening for cervical and breast cancer and for sexually transmitted infections (STIs) [7]. Although some women's health leaders have demonstrated that preventive screening is not necessary for the provision of hormonal contraception [8,9], in practice, many clinicians continue to link the services [10–12]. The high proportion of US women having had a recent Pap smear among those using nonhormonal contraceptive methods or not using a method at all suggests that women would likely continue to obtain these services [2]. However, no prior research has examined whether women obtaining OCs OTC have similar

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rates of reproductive health preventive screening compared to women obtaining OCs by prescription.

In this study, we assess the use of preventive screening services among US-resident women who have an OTC option for OC use. We take advantage of a natural experiment that exists along the US–Mexico border, where women can buy OCs OTC in Mexican pharmacies for as little as $5 per pack. Specifically, we evaluate whether the proportion of women obtaining preventive screening is different for women who access their OCs through this OTC option compared to women who obtain OCs with a prescription at a US family planning clinic, where such screenings are often required. We also examine women's reasons for not obtaining cervical cancer screening according to recommended guidelines.

2. Materials and methods

From December 2006 through February 2008, we recruited 1046 OC users into the Border Contraceptive Access Study [13]. Eligibility criteria were 18 and 44 years old, El Paso area residents, received their last pack of OCs from either a family planning clinic in El Paso or OTC at a pharmacy in Mexico and willing to complete a series of four interviews. Most OTC users and many clinic users were recruited using announcements, flyers, presentations at local community centers as well as through referrals; remaining clinic users were recruited from the major family planning providers in El Paso. After obtaining signed informed consent, we administered an hour-long face-to-face baseline interview using standardized questionnaires in either Spanish or English in the respondent's home. By the end of enrollment, we recruited 532 women who had received their last pill pack from a family planning clinic in El Paso and 514 who had received their last pill pack OTC in Mexico. We conducted two 20-min phone interviews approximately 3 and 6 months after baseline; 9 months after baseline, we conducted another face-to-face interview. Women received gift cards for completing each interview; those who completed all four interviews were compensated a total of $75 in gift cards. The study received approval from the Institutional Review Boards at both the University of Texas (UT) at Austin and UT-El Paso. At the end of data collection in December 2008, 941 women had completed the final interview, resulting in a retention rate of 90.0%. Of the 105 women who did not complete the final interview, the majority had moved out of the area, or we were unable to contact them (n=68); 37 women declined further participation.

The baseline questionnaire contained questions about the participant's race/ethnicity, marital status, parity, health status, medical history, Spanish- and English-language ability, educational status and place of birth. The questionnaire also included several items to assess the participant's use of health and welfare services in the USA and whether the participant had health insurance coverage. In the final interview, we asked whether she had been evaluated for a gynecological problem since baseline, as well as whether she had a Pap smear in the last 3 years; if yes, we asked where the test was performed, and, if not, the reasons for not having a Pap smear.

The analysis draws on questions from the baseline and final interviews. We use four dependent variables to assess use of preventive health services: had a Pap smear within the last 3 years, measured at the final interview; ever had a pelvic examination; ever been checked for STIs; and ever had a clinical breast exam (CBE), which were measured at baseline. Although we asked about Pap smears done in the previous 3 years at baseline, we use the measure for Pap smear history obtained at the final interview because that interview contained a question about why women had not obtained a Pap smear within the last 3 years.

All questions to assess use of preventive reproductive health screening included a description of the service. For instance, the Pap smear question included the following: "A Pap smear is when a doctor or nurse takes a sample of the cervix to test if you have abnormal cells that could develop into cancer." All questionnaires were piloted, and interviewers did not report that the respondents had difficulty comprehending these questions.

For this analysis, we excluded participants with missing data on relevant social and demographic characteristics or use of screening services (12 clinic and 16 OTC users), yielding a sample of 1018 women. We computed frequency distributions and χ^2 statistics for women's social and demographic characteristics according to women's source of OCs (clinic versus OTC). Next, we examined the bivariate relationship between women's source of OCs and use of screening services. Following current American College of Obstetricians and Gynecologists (ACOG) guidelines, we included only women aged 21 years and older in the Pap smear analyses (N=822). Similarly, since CBEs have limited accuracy in younger women [14], we restricted the analyses of CBE to women aged 40 years and over (aged 40–44 in our sample; N=120). The US Preventive Services Task Force (USPSTF) guidelines recommend testing for STIs among sexually active women younger than 25 years [15] (18–24 in our sample; N=292). Because of the lack of clear guidance on screening with a pelvic exam, we included all women (n=1018) in the analysis for having ever had a pelvic exam.

We then assessed the factors associated with obtaining screening using Poisson regression models with robust standard errors [16]. We chose this approach because the outcomes of interest are common and logistic regression would overestimate the relative risk [17,18]. Prevalence ratios estimated from Poisson models can be interpreted similarly to odds ratios in that values above 1 indicate that the outcome (i.e., receiving the preventive screening) is more common among participants with the factor under study. Previous analyses of these data revealed that clinic users were different from OTC users along several dimensions: clinic users were more likely to be younger, to have fewer

children, to have somewhat higher levels of education, to speak English more fluently than Spanish, to have been born in and completed their last year of schooling in the USA, and to have received assistance through government programs such as Women, Infants, and Children (WIC) and food stamps [13]. Therefore, since women self-selected their source of OCs rather than having been randomly assigned to each group, our analysis adjusted for the above characteristics that may predispose some women to choose one source over another. Because the Pap smear and pelvic examination analyses included a broad range of ages, we also include age as a predisposing characteristic in those models. In addition, our multivariable-adjusted analysis included women's *enabling characteristics* (receives government assistance, has health insurance in the USA, has a usual source of healthcare in the USA) and *need-for-care characteristics* [perceives health status as fair or poor, has any chronic condition (e.g., hypertension, diabetes, heart disease), was evaluated for a gynecological problem since baseline and had a pregnancy in the 12 months prior to baseline] [19]. For the gynecological problem indicator, we included a dummy variable to account for women who were lost to follow-up for the models of the three measures assessed at baseline. Because the sample is overwhelmingly Hispanic, we present the proportions in each group in the descriptive table, but do not adjust for this factor.

The target sample size for the study, 500 clinic users and 500 OTC users, was chosen to serve a number of purposes, with projected loss to follow-up of 10% at 3 months and 5% between each of the two subsequent interviews. With this sample size, using a two-sided alpha of 0.05 and assuming that 95% of clinic users had had a Pap smear in the past 3 years, we had 90% statistical power to detect an absolute difference of 6% in receipt of a Pap smear (i.e., 89% of OTC users having had a Pap smear in the prior 3 years).

3. Results

As noted above, participants who obtained their last pill pack in a US family planning clinic by prescription (*N*=516) differed from those who obtained them OTC from a pharmacy in Mexico (*N*=502) in most of their predisposing characteristics (Table 1). On average, clinic users were younger, had fewer births, had more years of schooling, were less likely to have completed their schooling in Mexico or to have been born in Mexico, and were more comfortable in English (all p<.05). Regarding characteristics that might enable women to obtain preventive screening, a higher percentage of clinic users were in households which received government assistance, but this difference was not statistically significant. Though low for both groups, a higher percentage of clinic users reported having health insurance and a usual source of healthcare in the USA. For characteristics that point to a participant's need-for-care, the only difference was that a

Table 1
Characteristics of participants by source of OCs at baseline

	US clinic *n*=516 (%)	OTC from Mexico *n*=502 (%)	χ^2 p value
Hispanic ethnicity	98.4	97.7	.342
Predisposing characteristics			
Age, years			
18–24	34.7	22.5	<.001
25–34	43.0	41.6	
35–44	22.3	35.9	
Parity			
0 live births	19.0	13.2	.039
1–2 live births	17.1	17.7	
3 or more live births	64.0	69.1	
Completed high school or higher	56.0	48.8	.022
Last year of schooling completed in Mexico	28.3	43.6	<.001
Born in Mexico	60.3	76.9	<.001
Language ability			
English better than Spanish	20.4	9.6	<.001
No difference	30.0	21.5	
Spanish better than English	38.8	56.2	
Spanish only	10.9	12.8	
Enabling characteristics			
Receives government assistance (WIC, TANF, food stamps)	75.4	70.5	.080
Has health insurance in the USA	23.6	12.2	<.001
Has a usual source of healthcare in the USA	53.3	34.3	<.001
Need-for-care characteristics			
Perceives health status as fair or poor	15.9	15.7	.946
Has any chronic condition[a]	4.3	5.4	.406
Evaluated for gynecological problem since baseline[b]	22.7	19.1	.197
Pregnancy in the 12 months prior to baseline	16.3	11.6	.030

WIC=Women, Infants, and Children; TANF=Temporary Assistance to Needy Families.
[a] Reported at least one of the following: high blood pressure, medication for high blood pressure, heart disease, diabetes, migraines, epilepsy or tuberculosis.
[b] Measured at the last interview; missing *n*=47 for clinic users and *n*=57 for OTC users.

higher percentage of clinic users had a pregnancy in the 12 months prior to the baseline interview.

With the exception of STI screening, the percentage of both clinic and OTC users who had received reproductive health preventive screenings was >88% (Table 2). For all outcomes considered, screening was more common among clinic users. For example, having had a Pap smear within the last 3 years was nearly universal among women aged 21 years and older who received their OCs from US family planning clinics, compared to 9 out of 10 women who received their OCs OTC from Mexico. Moreover, at the baseline interview, all clinic users and 97% of OTC users reported ever having a Pap smear (results not shown). Screening for STIs among women aged 18 to 24 years was

Table 2
Use of selected reproductive health preventive screening and unadjusted prevalence ratios, by source of OCs

Outcome (sample included)[a]	US clinic (%)	OTC from Mexico (%)	Prevalence ratio	χ^2 p value
Pap smear within last 3 years (age 21–44; n=822)[b]	99.3	90.8	1.09	<.001
Ever had a pelvic examination (age 18–44; n=1,018)	93.6	88.5	1.06	.004
Ever had a clinical breast examination (age 40–44; n=120)	100.0	88.9	1.12	.030
Ever been screened for STIs (age 18–24; n=292)	86.6	71.7	1.21	.002

  [a] Sample included reflects age range for current clinical recommendations, bounded by the age range of our sample (18 to 44 years).

  [b] Pap smear within the last 3 years measured at the final interview; all others measured at baseline.

somewhat lower: 87% of US clinic users and 72% of OTC users reported having been screened for STIs.

After adjusting for predisposing, enabling and need-for-care characteristics, prevalence ratios for all screening outcomes were higher among women who received their OCs from US family planning clinics compared to OTC OC users (Table 3) and were largely unchanged from the

unadjusted prevalence ratios shown in Table 2. The prevalence ratios for Pap smear were higher among women with a usual source of health care in the USA and among those who had a gynecological problem since baseline and a pregnancy in the 12 months before baseline. For the pelvic exam, prevalence ratios were higher among women with one child or more, those who completed at least a high school education and those with a pregnancy in the previous 12 months, and were lower among Spanish-only or Spanish-dominant speakers. In the adjusted model, having health insurance (versus no insurance) was associated with higher prevalence ratios for having had a CBE. In the model for STI screening, higher parity, higher education and being born in Mexico were associated with higher prevalence ratios for screening, as was having a chronic health condition; receipt of government assistance was associated with lower prevalence ratios for STI screening.

Table 4 shows large differences between the groups in the location of the last Pap smear. While nearly all the women who received their OCs from family planning clinics in the USA had their most recent Pap smear at a US clinic or other US site, over one in five OTC users had their last Pap smear in Mexico.

Reasons for not having had a Pap smear in the last 3 years for clinic and OTC users are presented in Table 5. Among OTC users who had not had a Pap smear within the last 3 years, the main reasons given were that Pap screening was

Table 3
Adjusted prevalence ratios and 95% confidence interval for obtaining selected reproductive health preventive screening among US family planning clinic OC users compared to OTC users

Independent variables	Outcome (sample included)							
	Pap smear within last 3 years (age 21–44)[a] n=822		Pelvic examination (age 18–44) n=1108		Breast examination (age 40–44) n=120		STI screening (age 18–24) n=292	
	PR	95% CI	PR	95% CI	PR	95% CI	PR	95% CI
Source (El Paso family planning clinic)	1.08***	1.05–1.11	1.05**	1.01–1.10	1.11**	1.03–1.19	1.22**	1.09–1.38
Predisposing characteristics								
Age	0.99	0.96–1.02	1.03	0.98–1.08	NA	NA	NA	NA
Parity (1 or more children)	1.03	0.97–1.09	1.22***	1.12–1.33	NA	NA	1.52***	1.29–1.81
Completed high school or higher	1.03	0.99–1.07	1.07**	1.03–1.12	0.99	0.88–1.11	1.19*	1.03–1.38
Last year of schooling in Mexico	0.98	0.94–1.03	0.99	0.95–1.05	1.06	0.96–1.17	1.02	0.83–1.24
Born in Mexico	0.99	0.95–1.04	1.04	0.99–1.10	1.00	0.75–1.34	1.17*	1.03–1.32
Language ability (Spanish only or Spanish better than English)	1.00	0.95–1.05	0.93**	0.89–0.97	1.04	0.86–1.25	0.91	0.78–1.06
Enabling characteristics								
Receives government assistance	1.00	0.95–1.04	0.95	0.90–1.00	1.00	0.92–1.10	0.80**	0.68–0.94
Has health insurance in USA	1.02	0.99–1.05	1.01	0.96–1.06	1.10*	1.00–1.22	1.11	0.97–1.26
Has a usual source of care in USA	1.04**	1.01–1.07	1.02	0.98–1.06	1.08	0.99–1.17	0.93	0.83–1.04
Need-for-care characteristics								
Perceives health status as fair, poor	1.02	0.99–1.06	1.00	0.95–1.05	0.87	0.75–1.02	0.97	0.84–1.13
Has a chronic health condition	0.99	0.91–1.07	0.95	0.86–1.05	1.05	0.90–1.22	1.32**	1.08–1.61
Gynecological problem since baseline (yes)	1.04**	1.01–1.07	1.03	0.99–1.07	0.94	0.78–1.13	1.09	0.97–1.22
Gynecological problem since baseline (missing)	NA	NA	0.95	0.88–1.03	1.09	0.99–1.21	0.94	0.78–1.14
Pregnancy in the 12 months before baseline	1.04**	1.01–1.07	1.07**	1.02–1.11	1.03	0.94–1.13	1.09	0.97–1.22

Reference categories are in parentheses. PR=prevalence ratio; CI=confidence interval; NA=not applicable.

*p<.05; **p<.01; ***p<.001.

  [a] Pap smear within the last 3 years measured at the final interview; all others measured at baseline.

Table 4
Location of Pap smear screening within the last 3 years

	US clinic n=400 (%)	OTC from Mexico n=422 (%)
US clinic	91.0	61.1
Doctor's office or elsewhere in USA	7.0	15.6
Mexico	1.8	21.6
Missing	0.3	1.7

too expensive or inconvenient or that they did not know where to obtain screening. Other reasons mentioned included that they kept "putting it off," did not believe a Pap smear was necessary, or fear or embarrassment about the test. A small number of women (n=5) said that they had not had a Pap smear in the last 3 years because their results were "always normal," because they did not have the proper residency documents to get the examination or because the Pap smear was not done during their regular examinations.

4. Discussion

As would be expected, among clinic users, we found nearly universal screening for cervical cancer among women aged 21 years and older. Ninety-one percent of women obtaining OCs OTC in Mexico also reported recent cervical cancer screening, which is higher than the US national average of approximately 85% for women aged 21–49 years [20]. Screening for breast cancer with a CBE among women aged 40 years and older was also universal for clinic users and close to 90% for OTC users. This compares favorably to research from a national sample of Hispanic women aged 30 years and older in which 53% had had a CBE [21]. Although STI screening was somewhat lower among OTC users, it still appears to be higher than for the general US population. While we found that 72% of OTC users aged 18–24 years reported STI screening, a recent prospective study of insured US women aged 15–25 years found that only 26% were tested for chlamydia over a 5-year period

Table 5
Reasons for not having Pap smear screening within the last 3 years

	US clinic n=6	OTC from Mexico n=48[a]
Too expensive	2	19
Too inconvenient	1	14
Keep putting it off	1	6
Does not know where to get it	0	5
Pap not necessary	1	4
Fear or embarrassment	0	3
Pap always normal	0	2
Does not have residency documents to get exam	0	2
Pap not done during exam	1	0

[a] Participants could state multiple reasons for not having screening in the last 3 years.

[22]. Since a minority of OTC users reported having US health insurance or a usual source of healthcare, one might have expected much lower rates of preventive screening. Taken together, these results are reassuring that women who obtain OCs without a prescription continue to get recommended preventive screening.

We found that even after controlling for other factors, clinic users still had significantly higher use of preventive screening services, although the magnitude of this difference was small. This finding is not surprising given that these screening tests are often standard practice at family planning clinics. In addition, women who had one child or more, higher education, health insurance, a regular source of care, or a chronic or acute condition (including recent pregnancy) were more likely to have received preventive screening compared to women with no children, less than a high school education, no health insurance, regular source of care, or chronic or acute condition, respectively. On the other hand, those with limited English ability and who received government assistance had lower use of screening compared to women who speak English well and those who did not receive government assistance, respectively. These results expand on those which found that health care coverage, continuity of care and physicians recommending a Pap smear were associated with increased cervical cancer screening among low-income minority women [19]. The fact that young women who were born in Mexico were more likely to have been screened for STIs may point to a perception among clinicians in this setting that foreign-born women are at higher risk than native-born women, though evidence from other sites suggests the prevalence of STIs among foreign-born women is lower than that among US-born women [23,24].

The reasons women gave for not obtaining a recent Pap smear suggest that barriers to access, such as the cost of services or not knowing where to obtain them, are the main factors preventing timely screening. An analysis of data from 11 states found that adequate health coverage was a significant predictor of obtaining screening for breast and cervical cancer [25]. Our prior analysis found that cost was a strong motivator for women obtaining OCs OTC in Mexico [13]. It is likely that at least some OTC users face barriers accessing family planning clinics in the USA, and these might be the same barriers that limit access to preventive screening. Indeed, this belief is supported by the fact that over 20% of OTC users obtained their last Pap smear in Mexico, where the service might be free or less costly than in the USA.

We included a question about pelvic examinations since this is often cited as a benefit of the annual exam that is linked with the provision of hormonal contraception. We found that a high proportion of both clinic users and OTC users had ever had a pelvic examination, although slightly more clinic users had received this exam. However, the routine pelvic examination is of limited utility as a screening test for ovarian cancer [26], and it is not recommended by the USPSTF [27]. In addition, results from demonstration

projects indicated that women would value having this requirement waived [8,28].

Our study has several limitations. Although we provided a description of screening services, we relied on women's self-reports of obtaining these tests, which may have over- or underestimated the true prevalence of screening. This is especially true for Pap smear and STI screening since women may not know precisely which tests were performed at the time of a pelvic exam and may have equated a speculum exam with these tests. We also cannot say precisely how well women were following ACOG guidelines for cervical cancer screening since we did not have information about the result of the Pap smear (which might necessitate more frequent screening) or a measure of having a Pap smear within the last 2 years for women aged 21 to 30 years. In addition, our findings are from one population in the USA and may have limited generalizability.

Overall, our results are encouraging that women would continue to obtain necessary preventive screening if OCs were available OTC in the USA. If barriers to access are an important reason why women fail to obtain recommended screening, it is likely that the prescription requirement for OCs only limits their access to contraception, rather than improving their access to screening. Therefore, a policy shift that allowed access to OCs through an OTC option could expand access to an effective contraceptive method, potentially reducing unintended pregnancies, while at the same time not having a detrimental effect on the uptake of reproductive health preventive screening. This evidence further strengthens the case for moving POPs, which have far fewer contraindications than COCs, OTC in the near future. It is clear that if POPs did become available OTC, it would be critical to develop an informational campaign that emphasized the importance of evidence-based preventive screening that would target women of all ages, incomes, races/ethnicities and language abilities. Indeed, under the Affordable Care Act, new private insurance plans will be required to cover without cost sharing women's preventive services, including cervical cancer screening, counseling and testing for STIs, as well as contraceptive methods and counseling [29]. It appears that FDA-approved OTC contraceptive methods, such as condoms and emergency contraception, will also be covered, although a prescription will likely be required to qualify for no cost sharing [28]. We hope that this prescription requirement can be removed in the future in order to reap the benefits of improved access that OTC availability at an affordable cost could provide.

Acknowledgments

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