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

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ABSTRACT

Context Interest is growing in the possibility of moving oral contraceptives over the counter (OTC), although concerns exist about whether women would continue to get needed preventive health screening, such as Pap smears.

Objective To compare the prevalence of reproductive health preventive screening for U.S.-resident oral contraceptive users who obtained their pills from U.S. public clinics with those who obtained them OTC from Mexican pharmacies.

Design, Setting and Participants Cohort study of 1046 oral contraceptive users in El Paso, Texas, interviewed 4 times over 9 months.

Main Outcome Measures Had a Pap smear within the last 3 years; ever had: a pelvic exam, clinical breast exam, testing for sexually transmitted infections. These outcomes were assessed using multivariable-adjusted Poisson regression models.

Results The prevalence of screening was high for both groups (≥88% for 4 of 5 measures), although the prevalence ratios for screening were higher for clinic users, even after multivariable adjustment. Twenty-two percent of OTC users had their last Pap smear in Mexico, compared to only 2% of clinic users. Among OTC users, reasons given for no Pap screening included inconvenience, cost, or not knowing where to get screening.

Conclusion These results suggest that most women would continue to obtain preventive screening if the pill were available OTC, and also highlight the importance of improving access to preventive screening services for all low-income women.

INTRODUCTION

The prescription-only status of oral contraceptives (OCs) in the United States (U.S.) requires women wishing to start or continue the pill to visit a clinician to be screened for appropriate use. While screening for the pill typically can be accomplished with a medical history and blood pressure check, many health practitioners require that women undergo yearly examinations in order to obtain a first or renew a prescription.[1] These examinations can include clinical breast examination (CBE), screening for sexually transmitted infections (STIs), cervical cancer screening, and bimanual pelvic examination. While some of these screening evaluations may be valuable for women of reproductive age, there is strong support for delinking them from the provision of hormonal contraception.[2]

Breast cancer is a contraindication to OC use,[3] but the CBE has poor accuracy to detect breast cancer, particularly among young women.[4] The U.S. Preventive Services Task Force (USPSTF) does not recommend routine screening for breast cancer before age 40; for women over 40 the USPSTF does not recommend for or against CBE, given the paucity of data.[5] Screening for STIs is especially important for women of reproductive age, particularly younger women who may have more than one sexual partner. The USPSTF recommends screening for STIs, especially chlamydia, among high risk groups, including all sexually-active women age 24 or younger.[6] The U.S. Centers for Disease Control recommends annual screening for chlamydia infection among all sexually active women aged ≤25 years.[7] However, having an STI is *not* a contraindication to OC use.

Although cervical cancer is also not a contraindication to OC use, clinicians often link pelvic examinations and cervical cancer screening to the provision of hormonal contraception. Current labeling of OCs does not require a pelvic examination to prescribe the pill; it can be deferred to a later examination.[8] In addition, nothing in the guidelines of the American College of Obstetricians and Gynecologists (ACOG) states that cervical cancer screening is a requirement for prescribing OCs. Furthermore the guidelines state that cervical cancer

screening no longer needs to be done yearly for most women and that screening should not begin before age 21. For women aged 21 to 30, screening should be done every two years, and for those over 30, screening can be done once every three years for women who have had three consecutive negative test results.[9] Nevertheless, a high proportion of U.S. physicians require recent cervical cancer screening prior to prescribing OCs.[10]

Some physicians also express concern about a drop in the use of preventive health services if the pill were made available over the counter (OTC), which is cited as one reason for maintaining the prescription-only status of the pill.[11] Though arguably it is unfair and paternalistic to require women to get screening services that are unrelated to pill use in order to obtain a prescription, the question still remains whether women in the U.S. would continue to get needed preventive health screening if the pill were available OTC. The high use of preventive screening among U.S. women who use non-hormonal methods or do not use a method at all suggests that women would likely continue to obtain these services.[12]

In this study we assess the use of preventive screening services among U.S.-resident women who have an OTC option for the pill. We take advantage of a natural experiment that exists along the U.S.-Mexico border, where women can buy pills OTC in Mexico 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 pills through this OTC option compared to women who obtain pills with a prescription at a U.S. family planning clinic, where such screenings are often required. We also examine women's reasons for not obtaining recent cervical cancer screening.

METHODS

From December 2006 through February 2008 we recruited 1,046 El Paso resident pill users aged 18 to 44 into the Border Contraceptive Access Study (BCAS).[13] Approximately half of these women (n=532) got their most recent pill pack from a family planning clinic in El Paso,

while the other half (n=514) got their last pill pack OTC in Mexico. Most OTC users and many clinic users were recruited using announcements, flyers, presentations at local community centers, as well as through referrals; the remainder of 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 or a place of her choosing. We conducted two phone interviews approximately three and six months after baseline, each of which took up to 20 minutes; nine 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 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, motivations to obtain pills from clinics or OTC, 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 U.S. and whether the participant had health insurance coverage. In the final interview, we asked about changes in health insurance, medical history, contraceptive use, and the use of health services. At this interview, we also asked about whether she had been evaluated for a gynecological problem since the baseline interview, as well as whether she had a Pap smear in the last three years; if yes, we asked where the test was performed, and, if not, the reasons for not having a Pap smear.

Measures

The analysis draws on questions from the baseline and final BCAS interviews. We use four dependent variables to assess use of preventive health services: had a Pap smear within the last three years, measured at the final interview; ever had a pelvic examination, ever been checked for STIs, and ever had a CBE, which were measured at baseline. Though we asked at baseline about Pap smears done in the previous three years, we use the measure for Pap smear history obtained at the final interview. We use the latter measure because, for women who had not obtained a Pap smear within the last 3 years, we followed it with a question about why they had not done so.

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" and for STIs, we asked: "Have you ever been checked for sexually transmitted infections (STIs) like chlamydia and gonorrhea?"

Analysis

For this analysis we excluded participants with missing data on relevant social and demographic characteristics or use of screening services (12 clinic and 12 OTC users), yielding a sample of 1,022 women. We computed frequency distributions and chi-square 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 ACOG guidelines, we included only women age 21 and older in the Pap smear analyses (N=826). Similarly, since CBEs have limited accuracy in younger women, we restricted the analyses of CBE to women age 40 and over (age 40-44 in our sample; N=120). USPSTF guidelines recommend testing for STIs among sexually-active women younger than 25 (18-24 in our sample; N=292). We include all women (n=1,022) in our 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.[14] We chose this approach because the outcomes of interest are common, and logistic regression would over-estimate the relative risk.[15, 16] The prevalence ratios estimated from Poisson models can be interpreted similarly to odds ratios in that values above one indicate that the outcome (i.e., receiving the preventive screening) is more common among participants with the factor under study. Since women self-selected their source of OCs, rather than having been randomly assigned to each group, our analysis adjusted for characteristics that may predispose some women to choose one source over another: parity, education, employment status, and language ability.[13] We also include age as a predisposing characteristic in our models of Pap smear and pelvic examination screening. In addition, our multivariable-adjusted analysis included women's *enabling characteristics* (receives government assistance, has health insurance in the U.S., has a usual source of healthcare in the U.S.), and *need-for-care characteristics* (perceived 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).[17] Because the sample is overwhelmingly Hispanic, we present the proportions in each group in the descriptive table, but do not adjust for this factor.

RESULTS

Participants who got their last pill pack in a U.S. family planning clinic by prescription differed from those who got them OTC from a pharmacy in Mexico on most of their predisposing characteristics (Table 1). On average, clinic users were younger, had fewer births, had more years of schooling, and were more comfortable in English (all $p < 0.05$). Regarding characteristics that might enable them to obtain preventive screening, a higher percentage of clinic users were in households in which a member received some form of 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 U.S. For characteristics that point to a participant's need-for-care, the only difference was that a 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 preventive reproductive health 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 three years was nearly universal among women age 21 and older who got their pills from U.S. family planning clinics, compared to 9 out of 10 women who got their pills 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, on the other hand, was lower among women aged 18 to 24: only 7 in 10 OTC users reported having been screened for STIs compared to over 8 in 10 U.S. clinic users.

After adjusting for predisposing, enabling and need-for-care characteristics, prevalence ratios for all screening outcomes were higher among women who got their pills from U.S. family planning clinics compared to OTC pill users (Table 3) and were largely unchanged from the unadjusted prevalence ratios. The prevalence ratios for Pap smear were higher among women with a usual source of health care in the U.S. 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 and education 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 got their pills from family planning clinics in the U.S. had their most recent Pap smear at a U.S. clinic or other U.S. site, over 1 in 5 OTC users got their last Pap smear in Mexico.

Reasons for not having had a Pap smear in the last three years for clinic and OTC users are presented in Table 5. Among OTC users who had not had a Pap smear within the last three years, the main reasons given were that Pap screening was too expensive, inconvenient, or they did not know where to get 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 three 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.

DISCUSSION

As would be expected, among clinic users we found nearly universal screening for cervical cancer among women age 21 and older. Ninety-one percent of women obtaining oral contraceptives OTC in Mexico also reported recent cervical cancer screening, which is higher than the national average of approximately 85% for women age 21-49.[18] Screening for breast cancer with a clinical breast examination among women age 40 and older was also universal for clinic users and close to 90% for OTC users, which compares favorably to 53% of CBE screening in a national sample of Hispanic women aged 30 and older.[19] Although STI screening was somewhat lower among OTC users, it still appears to be higher than for the general U.S. population. A recent prospective study of insured U.S. women age 15-25 found that only 26%

were tested for chlamydia over a 5-year period.[20] 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 mandatory 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, while those with limited English ability and who received government assistance had lower use of screening. 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.[17]

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 eleven states found that adequate health coverage was a significant predictor of obtaining screening for breast and cervical cancer.[21] 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 US, and these might be the same barriers that limit access to preventive screening. Indeed, this is supported by the fact that over 20% of OTC users obtained their last Pap smear in Mexico.

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,[22] and it is not recommended by the USPTF.[23] In addition, results from a demonstration project indicated that women would value having this requirement waived.[24]

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. 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 two years for women age 21 to 30 years. In addition, our findings are from one population in the U.S. and may have limited generalizeability.

Overall our results are encouraging that women would continue to obtain necessary preventive screening if the pill were available OTC in the US. 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. It is clear that if OCs 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, the new national health care reform plan may increase women's access to preventive health services with no cost-sharing.[25]

TABLES

Table 1. Characteristics of participants by source of oral contraceptives at baseline

	US Clinic	OTC from Mexico	
	n=520	n=502	Chi-square
	(%)	(%)	p-value
Hispanic ethnicity	98.4	97.7	0.345
Predisposing Characteristics			
Age			
18 – 24	34.4	22.5	<0.001
25 – 34	43.5	41.6	
34 – 44	22.1	35.9	
Parity			
0 live births	18.9	13.2	0.045
1 – 2 live births	16.9	17.7	
3 or more live births	64.2	69.1	
Completed high school or higher	56.0	48.8	0.022
Employed	39.2	35.5	0.213
Language ability			
English better than Spanish	20.4	9.6	<0.001
No difference	29.8	21.5	
Spanish better than English	39.0	56.2	
Spanish only	10.8	12.8	
Enabling Characteristics			
Receives government assistance (WIC, TANF, Food Stamps)	75.4	70.5	0.080
Has health insurance in the U.S.	23.7	12.2	<0.001
Has a usual source of healthcare in the U.S.	53.7	34.3	<0.001
Need-for-care Characteristics			
Perceived health status as fair or poor	15.8	15.8	0.989
Has any chronic condition[†]	4.2	5.4	0.391
Evaluated for gynecological problem since baseline*	22.5	19.1	0.228
Pregnancy in the 12 months prior to baseline	16.4	11.6	0.027

*Measured at the last interview; missing n=48 for clinic users and n=57 for OTC users.
[†]Reported at least one of the following: high blood pressure, medication for high blood pressure, heart disease, diabetes, migraines, epilepsy or tuberculosis.

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

Outcome (sample included)*	**US Clinic**	**OTC from Mexico**	**Prevalence Ratio**	
	(%)	(%)		Chi-square p-value
Pap smear within last 3 years (age 21-44; n=826)†	99.3	90.8	1.09	<0.001
Ever had a pelvic examination (age 18-44; n=1,022)	93.7	88.5	1.06	0.003
Ever had a clinical breast examination (age 40-44; n=120)	100.0	88.9	1.12	0.030
Ever been screened for STIs (age 18-24; n=292)	86.6	71.7	1.21	0.002

* Sample included reflects age range for current clinical recommendations, bounded by the age range of our sample (18 to 44).
† Pap smear within the last 3 years measured at the final interview; all others measured at baseline.

Table 3. Adjusted prevalence ratios and 95% C.I. for obtaining selected reproductive health preventive screening among U.S. family planning clinic oral contraceptive users compared to OTC users

Independent variables	Outcome (sample included)							
	Pap smear within last 3 years (age 21-44) †		Pelvic examination (age 18-44)		Breast examination (age 40-44)		STI screening (age 18-24)	
	P.R.	95% C.I.	P.R.	95% C.I.	P.R.	95% C.I.	P.R.	95% C.I.
Source (El Paso family planning clinic)	1.09***	1.05-1.11	1.05**	1.02-1.09	1.10**	1.03-1.18	1.21**	1.07-1.37
Predisposing characteristics								
Age	0.99	0.96-1.03	1.03	0.98-1.08	*N/A*	*N/A*	*N/A*	*N/A*
Parity (1 or more children)	1.02	0.97-1.08	1.23***	1.13-1.34	*N/A*	*N/A*	1.54***	1.30-1.83
Completed high school or higher	1.02	0.98-1.06	1.06**	1.02-1.11	0.99	0.88-1.11	1.18*	1.02-1.36
Employed	0.99	0.96-1.03	1.01	0.97-1.05	1.00	0.91-1.10	1.02	0.90-1.16
Language ability (Spanish only or Spanish better than English)	1.00	0.96-1.04	0.95**	0.91-0.98	1.02	0.89-1.17	0.97	0.86-1.10
Enabling characteristics								
Receives government assistance	0.97	0.95-1.04	0.96	0.91-1.01	1.00	0.91-1.09	0.80**	0.68-0.95
Has health insurance in U.S.	1.02	0.99-1.05	1.00	0.85-1.05	1.11*	1.00-1.22	1.07	0.94-1.21
Has a usual source of care in U.S.	1.04**	1.01-1.07	1.02	0.98-1.06	1.09	0.99-1.19	0.92	0.82-1.04
Need-for-care characteristics								
Perceives health status as fair, poor	1.02	0.99-1.06	0.99	0.94-1.04	0.87	0.75-1.02	0.96	0.83-1.11
Has a chronic health condition	0.99	0.91-1.07	0.95	0.85-1.05	1.04	0.89-1.20	1.26*	1.04-1.51
Gynecological problem since baseline (yes)	1.04**	1.01-1.07	1.03	0.99-1.07	0.95	0.80-1.12	1.08	0.96-1.21
Gynecological problem since baseline (missing)	*N/A*	*N/A*	0.95	0.88-1.03	1.10	1.00-1.22	0.93	0.76-1.13
Pregnancy in the 12 months before baseline	1.04**	1.01-1.07	1.06**	1.02-1.10	1.03	0.93-1.15	1.09	0.97-1.23
Number of observations	826		1,022		120		292	

† Pap smear within the last 3 years measured at the final interview; all others measured at baseline.
P.R. = Prevalence Ratio; C.I. = Confidence interval; NS=Not significant; N/A=Not applicable
*p<.05; **p<.01; ***p<.001

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

	US Clinic	OTC from Mexico
	N=404	N=422
	(%)	(%)
U.S. clinic	90.8	61.1
Doctor's office or elsewhere in U.S.	7.2	15.6
Mexico	1.7	21.6
Missing	0.3	1.7

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

	US Clinic	OTC from Mexico
	N=6	N=48*
Too expensive	2	19
Too inconvenient	1	14
Keep putting it off	1	7
Does not know where to get it	0	6
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

*Participants could state multiple reasons for not having screening in the last 3 years.

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