Oral contraceptive continuation along the US-Mexico Border: Does a prescription matter?

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Since their introduction nearly 50 years ago, oral contraceptive pills (OCPs) have become one of the most effective and widely used family planning methods worldwide. New, lower-dose formulations also make OCPs one of the safest options (Grimes 1992). The circumstances under which OCPs are sold to women, however, vary considerably across countries. One of the main differences is whether a doctor's prescription is required before a woman can purchase OCPs. In the United States (US), hormonal contraceptives require at least a health care provider's prescription if not a physical examination, which some public health experts consider unjustified (Stewart et al 2001). In neighboring Mexico, while OCPs are prescription-only in theory, in practice they are readily available from pharmacies without a prescription. Policy debate about relaxing the US prescription requirement for OCPs has focused on whether over-the-counter access (OTC) is safe and how it might influence use (Trussell et al. 1993; Grossman 2008; Jarvis 2008).

A specific question, still unresolved empirically, is what effect making the pill available over-the-counter in the United States might have on contraceptive continuation rates. Those who are against OTC access for OCPs have argued that medical supervision facilitates better use of the pill, and proper management of potential side effects. In this view, women accessing the pill at a pharmacy without a prescription would be likely to have lower continuation rates than women who were receiving the medical supervision that the prescription requirement ensures (Jarvis 2008). On the other hand, those in favor of OTC access have argued that the prescription requirement impedes access to this method of contraception, and that if the pill were available without a prescription at pharmacies continuation rates would actually increase on this account (Grossman 2008).

To assess the influence that OTC access might have on OCP continuation rates, we carried out a prospective survey of oral contraceptive users in El Paso, Texas--a unique setting along the US-Mexico border where US residents have the option of obtaining OCPs at pharmacies without a prescription at a cost of about US$5.00 per cycle. The border separating El Paso from Ciudad Juarez, Mexico is quite porous; four bridges link the two cities, and thousands cross frequently in both directions for commerce, family, recreation, education and services, such as health. Previous studies have established that health services in Mexico are an important resource for many residents in El Paso and other Texas border cities due to reasons such as lower cost, convenience, family networks, cultural comfort, perceived quality of care, and a different regulatory system (Amastae and Fernández 2006; Bastida et al. 2008; Fernández et al. 2007).

In El Paso, many US resident pill users obtain their OCPs from pharmacies in Ciudad Juarez without a prescription. In a postpartum survey carried out in the late 1990s, Potter and colleagues (2003) found that, in a sample of 1,312 multiparous lower-income mothers in

El Paso, 42% of pill users and 54% of injectable users procured their contraceptives in Mexico. In a more recent study of women's ability to self-screen for oral contraceptives using a convenience sample recruited at two shopping malls and a flea market in El Paso, 29 percent of 253 hormonal users, most of whom were on the pill, reported purchasing their method at a Mexican pharmacy (Grossman et al. 2008).

In addition to comparing OTC pharmacy users with clinic users, the information collected in our detailed baseline and follow-up questionnaires also allowed us to investigate an additional issue regarding the provision of OCPs that bears on the relationship between access and continuation. Foster et al. (2006) showed that, in California, women who were provided with 13 packs had higher continuation, and lower use of pregnancy tests compared to women who were given 1 or 3 cycles of pills. Chinn-Quee et al. (2009) compared provision of a single versus multiple packs of pills to new users in Jamaica, and also found that women provided with more pills had higher rates of continuation. If the number of pill packs a woman was given when she obtained pills effectively increases access and increases continuation, then it is important to control for this variable when comparing the continuation rates of clinic users with OTC (Mexican) pharmacy users.

In this paper, we present life table results that compare continuation rates over a nine month period for a sample of pill users who had obtained their pills at baseline at a family planning clinic in El Paso, Texas, USA with a sample of El Paso resident users who had obtained their pills over-the-counter at a pharmacy across the border in Ciudad Juarez, Chihuahua, Mexico. We then carry out a hazards analysis of method related discontinuation adjusting for education, duration of use and source at baseline, as well as three time varying covariates: marital status and parity, how long the woman planned to stay on the pill, and the number of pill packs at last supply.

Methods

Our goal was to recruit current pill users aged 18 to 44 stratified in two groups: 1) El Paso residents who use OCPs obtained at family planning clinics in El Paso (target n=500); and 2) El Paso residents who use OCPs obtained at pharmacies in Ciudad Juárez (target n=500). Most clinic users were recruited from the major family planning providers in El Paso such as the Women's Health Center at Thomason Hospital and four Planned Parenthood clinics in El Paso. However, recruiting pharmacy users at pharmacies in Ciudad Juárez proved to be impractical. In the end, virtually the entire pharmacy user sample and a considerable proportion of the clinic sample, were recruited using announcements, flyers, presentations at local community centers, as well as through referrals from current participants. The participants resided in over 30 different zip codes in the El Paso metropolitan area. The sample was not stratified by level of education or SES, but since it was limited to users of family planning clinics and users who obtained their pills from pharmacies in Ciudad Juárez, it did not typically include women who used their health insurance or personal funds to obtain prescriptions from private sector doctors and then bought their OCs at pharmacies in the US. In fact, the majority of study participants lived in sectors of the city where the average household income fell below the 2004 median income for the city.

After obtaining signed informed consent from participants who agreed to take part in the study, we administered an hour long face-to-face baseline interview. Bilingual project

staff conducted interviews in either Spanish or English in the respondent's home or a place of her choosing. Participants were offered a small compensation in the form of gift cards to a national chain store for completing the interview. This study was approved by the Institutional Review Boards at the University of Texas at Austin and University of Texas at El Paso.

The baseline questionnaire contained a wide range of items related to the participant's background: marital status, parity, health status, medical history, use of health services, knowledge of how to use the pill, contraceptive history, and reproductive intentions. Special emphasis was given to a series of items intended to gauge the participant's ability to take advantage of Mexican pharmacies as a contraceptive source such as her contacts and relationships in Mexico, her ability to speak Spanish, and the frequency with which she crossed the border. We also asked about the participant's country of birth, level of education and the country in which she completed her last year of schooling. The baseline questionnaire also collected detailed information on women's pill use history, focusing on their recent use. We asked for the month and year a participant obtained her last pack(s), the number of packs acquired at that time, where she got her pill packs, and whether she had ever asked someone else to buy pill packs for her in Ciudad Juárez.

The second and third interviews took place approximately three and six months after the initial interview. These interviews were administered via telephone and lasted 15-20 minutes. In the telephone interviews, women were asked about changes in their health and their pill use practice during the prior three months, as well as follow-up questions on contraceptive knowledge. The final (time 4) interviews are scheduled approximately nine months after the baseline interview. They were conducted in person, either in the participant's home or other location of her choosing and took about one hour to complete.

Recruiting for the study began in December 2006 and ended in February 2008, at which point we had successfully recruited over 1000 participants. In total, we collected 1046 baseline interviews (514 women who obtained OCs from Mexican pharmacies and 532 women who obtained OCs from El Paso family planning clinics), 965 time 2 follow-up interviews, 936 time 3 follow-up interviews, and 941 time 4 final interviews. Retention was a high priority, and we implemented a variety of strategies to attain this goal such as hiring interviewers with strong ties to the El Paso community, using an interview tracking system to identify when participants needed follow-up interviews, gathering extensive contact information, and providing modest incentives to women at the end of each interview. Overall retention for all rounds was 90%, with only 105 women lost to follow-up.

For this study, following Westhoff et al. (2007), we defined OCP discontinuation as having not taken any active oral contraceptive pill for more than seven days, and probed in each interview for any lapse of this or greater length. If the woman reported stopping, we asked for the date of discontinuation (day, month, year) as well as the reason for stopping. In addition to 13 precoded reasons, we probed with an open-ended question about why the respondent stopped. On the basis of both the precoded and textual responses, we recoded the reason for stopping into four categories: 1) got pregnant while using the pill, 2) stopped in order to become pregnant or because of no longer having a need for contraception, 3) to switch to another method, and 4) because of side effects, problems taking the pill, and other reasons. In the analysis, we distinguished between discontinuation for any reason, and discontinuation due either to pregnancy or a problem with taking the pill (categories 1 and 4) (Vaughan et al. 2008).

We separated exposure to the risk of discontinuation into separate segments corresponding to the intervals between interviews (approximately 90 days) for a maximum of three segments. Union status and how long a woman planned to continue using the pill were updated at each successive interview. We further divided these use segments for women who had resupplied between interviews on the date she reported last obtaining pill packs, and updated number of pill packs accordingly. While we are able to update source of contraception on the basis of information obtained during the follow-up interviews, for this analysis we hold source constant on the basis of whether the respondent was a clinic or pharmacy user at the baseline interview.

We estimate survivor functions for clinic and pharmacy users using nine 30 day periods. These are estimates of the fraction of the sample who continue to use contraception and are based on the elapsed time since the baseline interview rather than the overall duration of the segment. Estimates of the effects of risk factors are obtained from Cox proportional hazards models using Efron's (1977) method for handling tied event times. Proportionality tests are carried out using Schoenfeld (1982) residual tests. Additionally, we performed diagnostic tests for outliers and influential observations based on deviance residuals and martingale residuals (Therneau and Grambsch 2000).

Results

Our final analytical sample includes 965 subjects who completed a second interview, and thus contributed exposure for analysis. Of them, 493 were El Paso clinic users, and 472 were El Paso resident OCP users whose source at baseline was a pharmacy in Ciudad Juarez, Mexico. The distribution of these samples according to age, parity, education, nativity and place of last year of schooling, and duration of pill use at baseline is shown in Table 1. The table shows the proportion discontinuing use during the period of observation, as well the primary reason given for discontinuation. Note that there are surprisingly few pill users in this sample who have not had children, a characteristic of pill users in El Paso that appeared in an earlier sample of contraceptive users in El Paso and which differs considerably from the overall Hispanic or Mexican origin population of the United States (Potter et al. 2003).

The distribution of time-varying covariates for these segments is shown in Table 2. There are slightly more segments spent single among clinic users. On the other hand, there is a noticeable difference in the number of pill packs dispensed between the two samples. Pharmacy users are much more likely to have obtained only one or two cycles the last time they acquired contraception.

The life table results for all cause continuation are shown in Table 3 and Figure 1 separately for the two samples. The nine month continuation rates are high for both samples with 75 percent "surviving" (continuing to use pills) among clinic users, and 79 percent among pharmacy users. This difference is not statistically significant. The difference between the two samples increases somewhat for discontinuation due to pregnancy, side effects, or other reasons, as shown in Table 4 and Figure 2. There the nine month continuation rates in the associated single decrement life tables are 80 and 85 percent respectively, and the log-rank test for equality of survivorship tests can be rejected at $p=0.053$ level.

Before turning to the multivariate analysis of the risk of discontinuation due to an unplanned pregnancy, side-effects, or other method related reasons, we turn to the association we found in this study between the number of pill packs dispensed at last supply for clinic users with a composite variable based on parity and union status. Table 5 shows that mothers were much more likely to have been given six or more pill packs than were women who had not yet had a child, and that among mothers, those who were married or in union received more pills than did single or divorced or separated mothers.

For the hazards analysis, we wanted to see how discontinuation risk varied according to both of our access measures, clinic versus pharmacy source and number of pill packs received, adjusting for relevant controls and any significant covariates. Since the number of pill packs was a woman's choice among the pharmacy users, we only differentiate clinic users according to the number of pill packs received. Moreover, because the clinic might take the user's plans for future use into account, we included the woman's report as to how long she planned to stay on the pill in the model. Since the number of pill packs dispensed showed considerable variation according marital status and parity (Table 5), this categorization was also included as a control in the model along with duration of use at baseline and post-high school education.

Table 6 shows the estimated hazards ratios and p-values for El Paso clinic users according to the number of pill packs received at last supply relative to Mexican pharmacy users. Also shown are the estimated hazards ratios for the respective categories of the four covariates that were included in the final model. Compared to pharmacy users, the hazards of discontinuation for contraceptive failure or side-effects were 72 percent higher for clinic users who only received 1 or 2 pill packs, and 59 percent greater for those who received 3 to 5 packs. On the other hand, clinic users who received 6 or more pill packs had discontinuation rates that were 19 percent lower than those of pharmacy users, but this difference was not statistically significant.

Discussion

The first and main finding of this study is that continuation rates for El Paso resident OCP users who obtained their method from a pharmacy in Mexico were at least as high as those for a comparable sample of women who received OCPs from a family planning clinic in El Paso. Thus, this study lends no support to the proposition that withdrawing the prescription requirement for birth control pills would lead to lower continuation rates. Rather the results indicate that lowering access barriers increases contraceptive continuation. Indeed, the implication of our analysis is that both making pills available OTC and increasing the number of pill packs dispensed by clinics could help to increase OCP continuation rates in the US.

While the purpose of this study was to monitor a "natural experiment" whereby US residents had access to oral contraception without a prescription, we should note that the access El Paso residents have to this method of birth control is not completely equivalent to that which would be the results of making pills OTC in the US. On the one hand, the price per cycle of OCPs in Ciudad Juarez pharmacies is quite low, and to make OCPs available OTC at US$5.00 per cycle might not be feasible. On the other hand, having to cross an international border in order to get to a pharmacy is, at least for some users, a considerable

hurdle. Thus, a true OTC option for OCPs would likely provide considerably easier access than is currently available to El Paso residents.

Both a limitation and strength of this study is that it is restricted to a low-income, largely Hispanic population. It is clearly difficult to generalize these results to the entire population of pill users in the US. However, it is important to note that access appears to have a strong influence on continuation in such an underserved segment of the population. It is notable that, in these data, neither low levels of education nor being born or educated in Mexico were predictors of decreased continuation rates. Indeed, the only significant predictors of continuation found in this study were those related to access.

One parenthetical finding of this study is the relationship between the number of pill packs provided at a clinic and motherhood/marital status. We are inclined to believe that the strong association we found is the product of provider decisions or operating procedures rather than a reflection of differences in women's requests or expectations about how long they will use the pill. When asked at baseline, over 95 percent of clinic users in each of these groups said they expected to be using the pill for four or more months, and at least 85 percent in each group said they expected to be using the pill a year or more. Thus, in this setting, changing clinic policy to provide six or more pill packs to any client who expects to use the pill for at least six months could have an immediate and significant impact on continuation.

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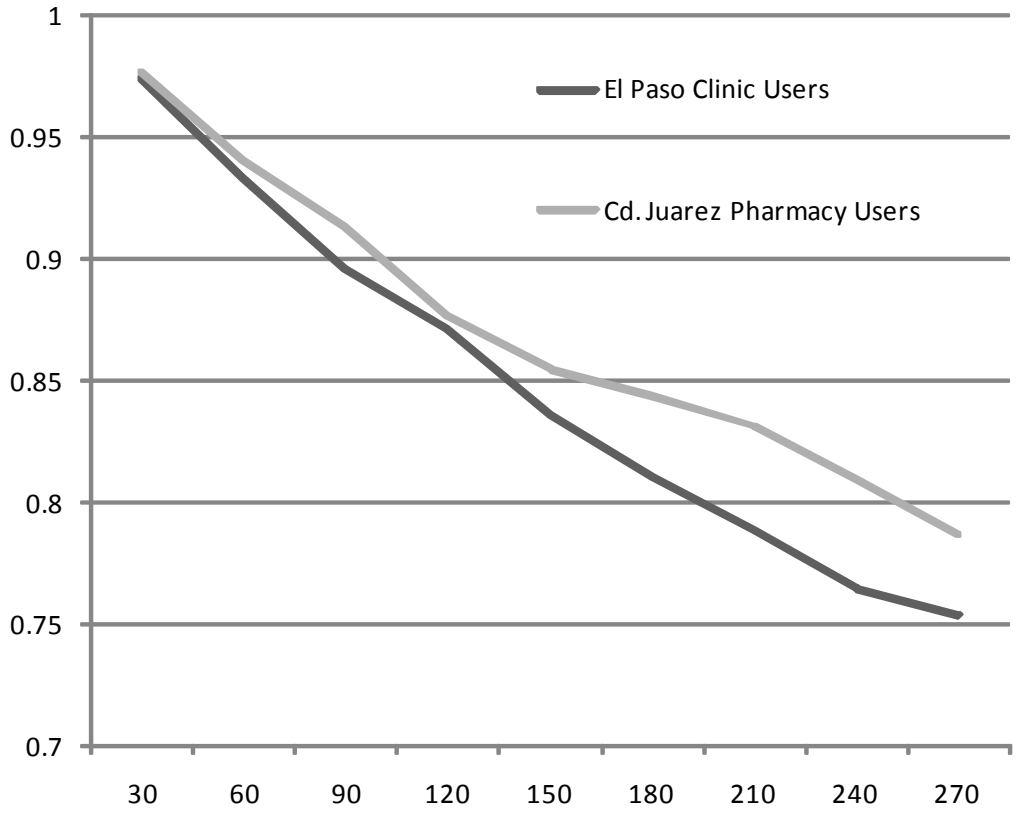

Figure 1. Pill Use Duration by Source of Pill: All Reasons for Discontinuation

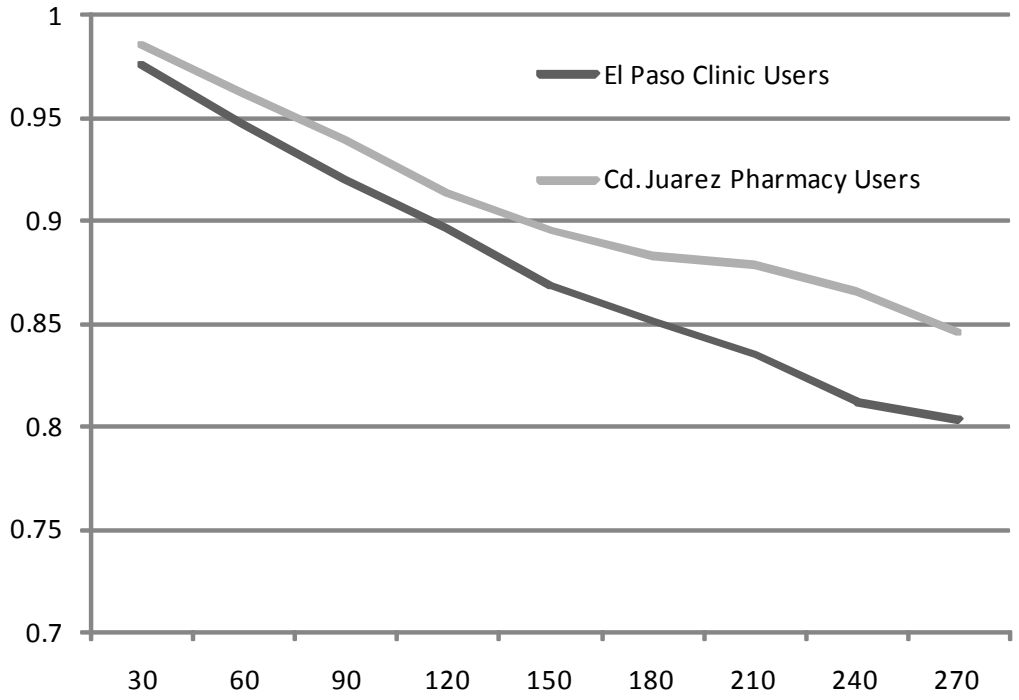

Figure 2. Pill Use Duration by Source of Pill: All Reasons for Discontinuation

Table 1. Characteristics of pill users by source of pill[1]

	El Paso clinic	Mexican pharmacy
	%	%
Age***		
18 – 24 years	34.1	21.6
25 – 34 years	43.4	42.8
35 – 44 years	22.5	35.6
Parity**		
0 live births	18.7	11.7
1 live birth	17.2	17.4
2 or more live births	64.1	70.9
Education**		
Less than 9th grade	15.0	23.6
9th-11th grade	28.4	27.8
12th grade	25.8	26.1
More than 12th grade	30.8	22.5
Nativity/Education***		
US-born	37.3	20.8
Mexican-born, US-educated	34.3	35.6
Mexican-born and educated	28.4	43.6
Duration of pill use at baseline		
Short duration (less than 200 days)	31.5	23.1
Medium duration (200-1500 days)	44.4	47.2
Long duration (greater than 1500 days)	24.1	29.7
Outcome Variables		
Discontinued pill use	31.0	24.6
Reason for pill discontinuation		
Got pregnant	15.7	16.0
Switched methods	4.1	9.0
Wanted to get pregnant	17.4	21.0
Side effects/other reasons	62.8	54.0
	(n=493)	(n=472)

[1]Source at baseline * p<0.05 ** p<0.01 ***p<0.001

Table 2. Time-varying characteristics of pill-users by source of pill[1]

	El Paso clinic	Mexican Pharm.
	%	%
Partner Status		
Married/Cohabiting	62.3	69.7
Single	37.8	30.3
Number of pill packs[2]		
1-2 pill packs	31.3	70.7
3-5 pill packs	35.9	25.7
6 or more packs	32.8	3.6
How much longer she plans to take the pill		
3 months or less	3.7	5.4
4-12 months	8.0	6.7
One year or more	88.3	87.9
	(n=2,377)	(n=2,117)

[1]Source at baseline
[2]Number of pill packs she last purchased

Table 3. Life table for discontinuation of the pill for any reason by source of pill[1]

	Start of interval	End of interval	Begin. total	Deaths	Lost	Survival
El Paso clinic						
	1	30	480	14	0	0.9736
	30	60	468	19	0	0.9329
	60	90	452	18	6	0.8961
	90	120	431	12	4	0.8713
	120	150	415	17	1	0.8358
	150	180	398	11	14	0.8102
	180	210	372	8	2	0.7884
	210	240	362	10	56	0.7646
	240	270	295	3	174	0.7536
Mexican pharmacy						
	1	30	461	11	0	0.9766
	30	60	450	17	0	0.9406
	60	90	432	13	4	0.9128
	90	120	416	15	0	0.8764
	120	150	404	10	0	0.855
	150	180	394	5	12	0.8441
	180	210	377	6	0	0.8308
	210	240	370	9	54	0.8093
	240	270	308	6	204	0.7863

[1]Source at baseline

Table 4. Life table for discontinuation of the pill due to pregnancy, side effects, or other reasons by source of pill[1]

	Start of interval	End of interval	Begin. total	Deaths	Lost	Survival
El Paso clinic						
	1	30	480	13	1	0.9756
	30	60	468	13	6	0.9469
	60	90	452	13	11	0.9198
	90	120	431	11	5	0.8964
	120	150	415	13	5	0.8683
	150	180	398	7	18	0.8505
	180	210	372	5	5	0.8344
	210	240	362	9	57	0.8117
	240	270	295	2	175	0.8039
Mexican pharmacy						
	1	30	461	7	4	0.9851
	30	60	450	11	6	0.9614
	60	90	432	10	7	0.9395
	90	120	416	10	5	0.9129
	120	150	404	8	2	0.895
	150	180	394	5	12	0.8836
	180	210	377	2	4	0.8789
	210	240	370	5	58	0.8662
	240	270	308	5	205	0.8456

[1]Source at baseline

Table 5. Number of pill packs[1] by parity/marital status: El Paso clinic users only

	Has children/single	Has children/married	No children
	%	%	%
Number of pill packs***			
1-2 packs	26.7	25.3	56.0
3-5 packs	42.2	35.5	29.5
6 or more packs	31.2	39.2	14.6
	(n=465)	(n=1,244)	(n=403)

[1]Number of pill packs she last purchased * p<0.05 ** p<0.01 ***p<0.001

Table 6. Cox proportional hazard models for pill discontinuation due to pregnancy, side effects, or other reasons

	Hazard Ratio	P-Value
Source of Pill/Number of Pill Packs[1,2]		
Mexican pharmacy	1.00	
El Paso clinic/1-2 packs	1.72	0.02
El Paso clinic/3-5 packs	1.59	0.04
El Paso clinic/6 or more packs	0.81	0.45
How long she plans on taking the pill		
3 months or less	1.00	
4-12 months	0.77	0.50
1 year or more	0.41	>0.01
Duration of pill use at baseline		
1 to 200 days	1.00	
201 to 1500 days	1.18	0.42
Greater than 1500 days	0.71	0.19
Education		
Less than high school	1.00	
High school or more	1.37	0.12
Parity/Marital Status		
Has children/single	1.00	
Has children/married	0.73	0.14
No children	0.88	0.63

[1]Source at baseline
[2]Number of pill packs she last purchased