Prevalence of Contraindications to Oral Contraceptives and Efficacy of a Self-Screening Instrument in a Predominantly Hispanic Sample

Daniel Grossman, MD
Ibis Reproductive Health, San Francisco

Leticia Fernandez, PhD
Department of Sociology and Anthropology
Center for Interamerican and Border Studies
University of Texas at El Paso

Kristine Hopkins, PhD
Population Research Center
University of Texas at Austin

Jon Amastae, PhD
Center for Interamerican and Border Studies
University of Texas at El Paso

Kari White, MA, MPH
Population Research Center
University of Texas at Austin

Sandy Garcia, ScD
Population Council, Mexico Office

Joseph E. Potter, PhD
Population Research Center
University of Texas at Austin

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ABSTRACT

This study measures the level of contraindications in a sample of predominantly Hispanic women on the US-Mexico border. We also compared women's ability to screen themselves for contraindications to those of a health professional. We interviewed 1,357 women 18-49 years old, recruited from shopping malls in El Paso, Texas. We found that 42.6% of women were contraindicated to the pill, higher than previous studies have found. A question asking a woman if she thought the pill was medically safe for her correctly identified 55% of women with true contraindications. Using a medical checklist of contraindications, women were more accurate in their self-assessments; respondents correctly identified contraindications 79% of the time. Younger women were better at self-screening than older women. Current hormonal users were also better at self-screening, suggesting that over-the-counter access for women seeking refills who have already been screened by a clinician would be particularly safe.

INTRODUCTION

Oral contraceptives (OCs) are one of the safest and most effective family planning methods available. Women in many countries are able to purchase OCs without a health care provider's prescription, and studies suggest that efficacy and continuation are not adversely affected by over-the-counter provision (Grossman et al 2006). However, in the United States a prescription, and often a physical exam, is required. These criteria for obtaining OCs may present a barrier to timely initiation of contraception, or completely prevent access to women who are under- or uninsured (Shotorbani et al 2006; Pharmacy Access Partnership 2004). These barriers raise additional concern given that nearly two-thirds of pregnancies in the United States are unintended (Samuels and Smith 1994). An analysis that compared the most recent National Surveys of Family Growth found that rates of unintended pregnancy rose disproportionately among women of color and low income women between 1995 and 2002 (Guttmacher Institute 2006).

Debates surrounding over-the-counter availability of oral contraceptives in the US have focused on issues of safety and a woman's ability to effectively screen herself for contraindications to OC use. Eliminating the prescription requirement would potentially lead to the use of OCs among women for whom it is not medically appropriate. Even among those for whom OC use is contraindicated, however, and who would potentially lose access to a mandatory professional

judgment of that fact, the risks of unintended pregnancy typically outweigh those of OC use (Trussell et al 1993). The WHO recently recommended birth spacing of at least two years after a live birth in order to reduce the risk of poor maternal, perinatal and neonatal outcomes (WHO 2005), and improved access to OCs might allow women to more effectively prolong the interval between their pregnancies. Additionally, the non-contraceptive benefits conferred by OCs, such as reduced risk of certain reproductive cancers and diseases, also need to be included in assessments for determining over-the-counter access (Hatcher and Guillebaud 1998).

The purpose of this study is to determine the level of contraindications in a sample of predominantly Hispanic women on the US-Mexico border as well as whether women can screen themselves for contraindications as well as a health professional can. In addition, this study was designed to clarify the role that a simple, self-administered checklist can play in helping women to determine whether OCs are safe for them. Specifically, the objectives of this study were to: (1) describe the accuracy of a woman's unaided self-assessment of eligibility for oral contraceptive use; (2) determine the accuracy of her self-assessment after completion of a medical screening checklist; and (3) compare both of these results with a health care professional's assessment, he presumed "gold standard"

SELF-SCREENING FOR CONTRAINDICATIONS

Very few studies have examined whether women can screen themselves for medical contraindications to OC use. In two studies from Mexico, where OCs are easily available over-the-counter, authors have demonstrated that women who obtain their pills over-the-counter at pharmacies have similar risk profiles to women who receive pills from private practice or public clinics (Zavala et al. 1987; Yeatman, Potter and Grossman 2006). Zavala et al (1987) found that women who obtained pills from a community-based distribution program had similar health profiles and prevalence of risk factors compared to those who obtained their pills from other locations, such as pharmacies. These findings indicate that women who had not consulted with a physician were just as well-screened as those women who had received a formal medical evaluation. Using data

from the Mexican National Health Survey, Yeatman, Potter and Grossman (2006) compared the health profiles and contraindications to pill use among women obtaining OCs from pharmacies and those who received pills from a public or private clinic. Although women who obtained pills from clinics had fewer contraindications to pill use than those who purchased their pills directly from pharmacies, the differences between these groups were not statistically significant. Furthermore, the authors' analysis from the Mexican National Survey of Reproductive Health showed that the majority of women (69.2%) who currently purchased OCs at pharmacies had begun use under medical supervision through a private doctor or public clinic.

In a recent US study, Shotorbani et al (2006) demonstrated that women's responses to a medical eligibility checklist for hormonal contraceptives was just as accurate as a provider's formal evaluation. In an item-by-item analysis, agreement ranged from 84% to 100% between a woman's self-assessment and the provider's assessment of whether she had a given contraindication. Furthermore, the authors showed that where women and providers disagreed, women were *more* likely to report contraindications than were providers. These included such criteria as severe headaches, possible pregnancy and smoking - absolute contraindications under the 2004 WHO guidelines. Of note, less than 5% of the women in this study were judged to be contraindicated to hormonal contraceptive use.

Although all these studies demonstrate the general effectiveness of women to screen themselves for contraindications for OC use, the populations used in these studies were restricted to women already using oral contraception or accessing family planning services. Therefore, it is possible that women who had already screened themselves out of oral contraceptive use were not included. In this study, we survey both OC users and non-users, to reduce the possibility of selection bias.

The border cities of El Paso, Texas and Ciudad Juárez, Chihuahua provide such a sample. The two cities form the world's largest urban concentration on a land border. El Paso's population is roughly 80% Hispanic/Latino; it is also quite young, with about 90% of individuals under the age of

65 and 32% under age 18 (2000). A majority of El Paso's Hispanic population is bilingual. Like El Paso, Ciudad Juarez's population is also generally young with about 75% of the population under 35 years old. The total population of the borderplex exceeds 2 million. El Paso County is the third-poorest county in the U.S. (behind two other Texas border counties), and it lags national norms of economic and social well-being. While Ciudad Juárez is poorer than El Paso, it is well ahead of Mexican norms of economic well-being. Its economy is now based on the *maquiladora* industry and trade with the U.S. Both communities have experienced high rates of growth and change since the passage of NAFTA in 1994.

El Paso and Ciudad Juárez are an ideal environment for gathering data and testing hypotheses concerning access to healthcare services. A long history of wide-spread interaction and interdependency has created a heightened regional consciousness that includes common practices of accessing a nearly complete menu of services on both sides of the international line among some groups. Although this area of research is incipient, it has been suggested that crossborder practices result from perceived benefits or inhibitors of many types, including the obvious time and cost constraints. At the same time, despite the demographic and cultural similarities, and the historically-relaxed border that has facilitated interaction, the two populations exist within very different regulatory regimes for healthcare, and consequently two different sets of officially sanctioned and created healthcare cultures and messages. Thus, a robust sample of this population offers an excellent opportunity to tease out the factors that influence healthcare behavior that may be matters of culture, economics, convenience, regulatory system or others.

METHODS

Target Sample Size

Based on data from the 1998 National Health Interview Survey, we estimated that approximately 15% of women of reproductive age in the general population are contraindicated for OC use (Pleis and Coles 2002; Schoenborn, Vickerie and Barnes 2003). For this study, we sought to determine if 1% of the population or more might falsely believe that OCs are appropriate for them

when in fact they are medically contraindicated. We determined that a sample size of 1,200 would give us 95% confidence interval of this measurement of +/- 0.6%.

Instruments

We use a medical checklist based on World Health Organization (WHO) medical eligibility criteria (WHO 2004), using WHO's relative and absolute contraindications to oral contraceptives (classification 3 and 4). We did not include conditions that are considered classification 2, as the WHO states that in situations with limited clinical judgment it is reasonable to use the method. Table 1 lists the questions included in the checklist.

Participants

In order to sample a relatively large number of women of reproductive age in the general population, a convenience sample was used. Data collection was performed between April and August 2006. Bilingual (English/Spanish) female interviewers approached women in two public shopping malls and an outdoor flea market in El Paso, Texas and invited them to participate in the study. Women between 18 and 49 years of age and able to complete the interview in English or Spanish were eligible to participate. A total of 1,357 women agreed to participate. Information on refusal to participate was not collected, but study staff reported that very few women declined to participate in the survey.

Interviewers asked women about basic sociodemographic information as well as about their current contraceptive use. We then asked all women who were not current hormonal contraceptive users if they thought the pill would be an appropriate birth control choice given their medical history and regardless of their intent to use this method. We assumed that hormonal users would consider pill use safe for them, and were therefore not asked the question. Next, all women were given the medical checklist of contraindications to oral contraceptives. Respondents reviewed this list and marked yes for each "…condition that might make it more likely for you to develop a problem while taking the Pill."

After completing the questionnaire, women were screened by a nurse practitioner, blinded to the woman's responses in the interview. One of five female providers evaluated each woman who completed a questionnaire. The provider's screening questionnaire included, in addition to background demographic information, a medical history that focused on the same contraindicated conditions identified in the WHO criteria. The nurse practitioner also measured and recorded the respondent's blood pressure either manually or using an automated Omron HEM-705CP blood pressure monitor (Omron Healthcare, Inc., Bannockburn, Illinois). Based on this information, she determined if the respondent was an appropriate OC user. If the provider felt that additional tests or evaluation was necessary before prescribing OCs, the respondent was classified as contraindicated. The medical checklist and questionnaires were initially piloted with 80 women to ensure that they were understandable. Because only minimal changes were made to the instruments after the pilot, these data were included in the analysis.

Participants received a $5-$10 gift card valid for use at the shopping center or flea market for their participation. The study was approved by the Institutional Review Boards of the University of Texas at Austin and the University of Texas at El Paso. We obtained verbal informed consent from all participants.

Data analysis

Questionnaire data were entered into a Microsoft Access (Seattle, WA, 2000) database and analyzed using Stata version 8 (College Station, Texas). Univariate descriptive statistics were generated to characterize the study participants and to describe the overall distribution of responses. We used the point-estimate and 95% confidence interval (CI) to measure participant–provider agreement. The criteria used to define agreement included either "yes/yes" or "no/no" participant–provider responses to each question. We used logistic regression to model the outcome variable of interest (participant–provider agreement) and to estimate agreement among subgroups defined by age, language preference, education, parity and contraceptive use.

RESULTS

Table 2 shows the demographic characteristics of the study participants. The participants, on average, were in their early thirties, had completed 13 years of schooling and had between one and two children. The sample is overwhelmingly Latina and the majority primarily speak Spanish or speak it equally with English. Four out of five of the respondents live in the US and two-thirds completed their schooling in the US. A small fraction of participants suspect a current pregnancy.

In total, the providers found that 43.2% of respondents were medically contraindicated to OC use, whereas women's self-assessments of contraindications varied from 47.2% for the initial self-screen to 40.1% with the self-screening checklist (Table 3). In looking at the accuracy of the initial screening question, 716 (52.8%) said the pill was medically safe for them and 641 (47.2%) said it was unsafe or they were not sure. The overall sensitivity of this screening question to detect a true contraindication compared to the provider screen was 55.4%, and the specificity was 59.0%. Using the medical checklist, we found that 84.8% of woman-provider pairs were in agreement regarding their overall assessment of medical eligibility to use OCs (presence of one or more contraindication vs. absence of any contraindication). Eighty women (6.0%) using the checklist considered themselves contraindicated for pill use, when in fact the provider determined they were eligible. On the other hand, 122 women (9.1%) failed to identify a true medical contraindication using the checklist.

Table 4 shows both the level of contraindications in this sample and the respondent-provider agreement (eligible-eligible or contraindicated-contraindicated) for several conditions on the medical checklist. By summing the two cells in which the provider determined a contraindication (the second and fourth rows), we can see the proportion of respondents who were contraindicated for pill use for by individual conditions. Less than 1% of respondents were contraindicated for pill use due to diabetes or gall bladder disease and 4.4% of respondents were contraindicated due to smoking. But hypertension was a contraindication for 14.5% and migraine for nearly 18% of respondents. Of the four conditions listed, only hypertension and migraine headaches show much respondent-provider

disagreement. In the case of hypertension, 9% of the respondents were found to be hypertensive (systolic blood pressure $\geq$ 140 mm Hg or diastolic blood pressure $\geq$ 90 mm Hg) and did not know this to be the case. With migraines 6% of the respondents believed their condition made them ineligible to use the pill. The provider, however, determined that these women did not have migraine with aura, which is the true contraindication. For the contraindications not shown in Table 4 the agreement was 98%-99% between self-screening and the NP screen.

Table 5 shows the adjusted odds ratios from logistic regressions to assess the association between selected demographic characteristics and respondents' incorrect self-assessment of (a) hypertension and (b) one or more contraindications to pill use.

Hypertension: The first two columns in Table 5 show the coefficients in the models for women who incorrectly reported themselves as hypertensive and women who incorrectly reported no hypertension. We find that the odds of incorrectly reporting no hypertension increased significantly with age. Women in the older age group in the sample (45 to 49) were more than five times more likely than those age 30 and younger to incorrectly report that they do not have hypertension. Women who speak Spanish at home were less likely to incorrectly report no hypertension compared to those who prefer English. Neither education, parity or contraceptive method were associated with incorrect assessment of hypertension among study participants.

Presenting one or more contraindications to pill use: The last two columns in Table 5 show similar findings for women who incorrectly assessed their eligibility for pill use due to one or more conditions. Again we find age and language used at home to be a significant factors. Women ages 35 and older were significantly more likely to incorrectly report that they were eligible for pill use compared to younger women. As was the case for hypertension, those reporting Spanish as the primary language used at home were less likely to incorrectly report that they are eligible for pill use. Other variables in the regression were not significantly associated with the odds of either incorrectly reporting contraindications or incorrectly reporting pill eligibility.

DISCUSSION

Very few data are available on the prevalence of contraindications among the general population of women of reproductive age. One study from Washington found that among women presenting to a family planning clinic, 4.6% were found to be contraindicated to hormonal contraception (Shotorbani et al 2006). In the population reported here, we found that 42.6% of women were contraindicated to oral contraceptives (OCs). While it is certainly surprising that the prevalence of contraindications is ten-fold larger in our population, there are important differences between the two groups. Eighty-eight percent of the women in the Washington study were seeking hormonal contraception, and 90% were between the ages of 15 to 30. Our population was older, which increases the likelihood of being contraindicated to OCs, and was much less likely to be using hormonal contraception and therefore less likely to have been previously screened for contraindications. The prevalence of contraindications reported here is closer to that reported using data from a national health survey in Mexico (Yeatman et al 2006), although that study was not able to include migraine with aura as a contraindication.

The main conditions that contributed to being contraindicated to OCs were hypertension, migraine with aura, previous bad reaction to the pill, and other severe medical problems reported by the respondent. It is important to note that only the first condition is possibly unknowable to the woman. In the case of migraine with aura, we found that women were more likely to self-screen themselves out of OC use, when in fact the nurse practitioner did not feel that the respondent's headaches contraindicated pill use, a finding that has been reported previously (Shotorbani et al 2006). Similarly, women who were diagnosed by the provider with a previous bad reaction to the pill or other severe medical problem that contraindicated OCs largely excluded themselves from pill use by stating that the pill was unsafe for them.

A simple question asking a woman if she thought the pill was medically safe for her correctly identified 55% of women with true contraindications. Using a medical checklist of contraindications, women were more accurate in their self-assessments; respondents correctly identified

contraindications 79% of the time and the specificity of the screening tool was 90%. The low specificity of the initial self-screening measure ("is the pill bad for your health?") is of concern because it shows that a large number of women decide that OCs are not appropriate for them when in fact they are not medically contraindicated. The reduced specificity in the initial screening reflects misconceptions about the medical risks of the pill as well as previous bad experiences with OCs. In particular, we found that women who primarily speak Spanish at home were significantly less likely than English-speakers to erroneously think they did not have a contraindication when they truly did. This suggests that the Spanish-speaking population overestimates the risks associated with hormonal contraception. Prior studies have documented that concerns about side effects and long-term health effects are a major reason why women choose not to contracept (Ali and Cleland 1995; Agyei, Mukiza-Gapere and Epema 1994; Parr 2003). Future research should further elucidate these negative impressions of hormonal contraception and test interventions to improve women's perceptions of the pill.

Some women were found to be better at self-screening than others. Younger women were better than older women, largely because older women more commonly were hypertensive without knowing it. Women already using hormonal contraception were also more accurate in their ability to self-screen than users of other methods or non-contraceptors. This finding suggests that over-the-counter access for women seeking refills who have already been screened by a clinician and prescribed a hormonal method in the past would be particularly safe. Finally, more educated women were also found to be more accurate self-screeners. Interestingly, a study of data from Mexico found that women who obtained oral contraceptives over the counter were more educated than those who obtained pills from a clinic (Yeatman et al 2006).

Overall, these findings suggest that women can, by and large, accurately self-screen for contraindications to pill use, when the contraindications are listed individually. Moreover, women who are likely to seek contraception—especially younger women—are able to identify conditions that might make OC use dangerous. If anything, self-screening may eliminate more people as OC

candidates than clinician screening. In an over-the-counter environment, however, women who wanted to use the pill and find that they are contraindicated by self-screening would likely seek the counsel of a clinician rather than deciding definitively that the method is dangerous for them. An actual use study of oral contraceptives provided in a simulated over-the-counter setting is needed to answer these remaining questions.

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TABLES

Table 1. Participant Self-Screening Checklist for Medical Contraindications

1.	Are you a smoker age 35 or older?
2.	Do you think you might be pregnant?
3.	Have you had a baby in the past 3 weeks?
4.	Are you currently breastfeeding ***and*** your baby is less than 6 months old?
5.	Do you have high blood pressure?
6.	Have you had a heart attack or stroke?
7.	Do you have heart disease?
8.	Have you had a blood clot (thrombosis) in your lung or in your leg (NOT just varicose veins)?
9.	Do you have diabetes?
10.	Do you have migraine headaches?
11.	Do you have liver disease or have you had liver cancer?
12.	Do you have gall bladder disease?
13.	Have you had breast cancer?
14.	Do you take medicine for high cholesterol?
15.	Do you take medicine for seizures or tuberculosis (TB)?

Table 2. Demographic Characteristics of Study Participants (N=1,357)

	N	%
Age, years (mean=32.6; median=32)		
≤24	343	25.3
25-34	435	32.1
35-49	579	42.7
Race/Ethnicity		
Latina	1,240	91.5
African American	30	2.2
White	57	4.2
Other	29	2.1
Primary language used at home		
Spanish	668	49.2
English and Spanish, equally	165	12.2
English	524	38.6
Primary country of residence		
United States	1,094	80.6
US and Mexico, equally	9	0.7
Mexico	243	17.9
Other	11	0.8
Education (mean=13.1, median=13)		
Incomplete high school or less (0-11 yrs)	256	18.9
Completed high school	335	24.7
Some college (13-15 yrs)	376	27.7
College or more	390	28.7
School location for last grade completed		
United States	901	66.6
Mexico	432	32.0
Other	19	1.4
Parity (mean=1.5; median=2)		
Nulliparous	446	32.9
One	209	15.4
Two	365	26.9
Three or more	336	24.8
Suspects current pregnancy[1]		
Yes	63	4.7
No	1,293	95.4
Current Contraceptive Use		
Sterilization	369	27.2
Oral contraceptive pills	207	15.3
Condoms	120	8.8
Injections	47	3.5
IUD	38	2.8
Patch	16	1.2
Other barrier method	5	0.4
Spermicides (i.e. foam, film)	2	0.2
Vaginal ring	2	0.2
None: Not sexually active	229	16.9
None: Trying to get pregnant	99	7.3
None: Other reason	223	16.4

[1] Question in self-assessment was “Do you think you might be pregnant?”

Table 3. Comparison and Accuracy of Self-Screening Compared to Provider Screening for Contraindications to Use of Oral Contraceptives

Panel 1: Initial self-screen[1] % (95% C.I.)		Provider		
		Contraindicated	Eligible for pill use	Total
Respondent	Contraindicated	23.9 (21.6-26.1)	23.3 (21.1-25.6)	47.2 (44.5-49.9)
	Eligible for pill use	19.2 (17.1-21.4)	33.6 (31.0-36.1)	52.8 (50.1-55.5)
	Total	43.1 (40.5-45.8)	56.9 (54.2-59.5)	100.0
Sensitivity = 23.9 / 43.1 = 55.4%; 95% CI: (51.2-59.5) Specificity = 33.6 / 56.9 = 59.0%; 95% CI: (55.4-62.5)				

Panel 2: Self-Screening checklist[2] % (95% C.I.)		Provider		
		Contraindicated	Eligible for pill use	Total
Respondent	Contraindicated	34.1 (31.5-36.6)	6.0 (4.7-7.2)	40.1 ()
	Eligible for pill use	9.1 (7.6-10.1)	50.8 (48.1-53.5)	59.9 (57.3-62.6)
	Total	43.1 (40.6-45.9)	56.8 (54.1-59.4)	100.0
Sensitivity = 34.1 / 43.1 = 78.9%; 95% CI: (75.2-82.1) Specificity = 50.8 / 56.9 = 89.5%; 95% CI: (87.0-91.5)				

[1] Initial self-screen refers to women's answer to the question whether the pill would be bad for their health. Hormonal contraceptive users were, by default, classified as deciding that they were eligible for pill use.

[2] Self-screening checklist refers to women's yes/no answers to the medical checklist of possible contraindications to pill use. Women were classified as self-contraindicated if they checked "yes" to any of the items on the list.

Table 4. Respondent-Provider Agreement on Selected Contraindications for Oral Contraceptive Use[1]

Comparison between self-screen and provider screen	Contraindication				
	Smoking & age >35 N=1,353	**Hyper-tension** N=1,356	**Diabetes** N=1,355	**Migraine headaches** N=1,357	**Gall bladder disease** N=1,356
Self-screen and provider screen agree: eligible for pill use	93.7	83.6	97.1	76.3	98.2
Self-screen and provider screen agree: contraindicated	4.1	5.5	0.7	17.0	0.4
Self-screen contraindicated; provider screen eligible for pill use	1.9	1.9	2.3	6.1	1.2
Self-screen eligible for pill use; provider screen contraindicated	0.3	9.0	0.0	0.6	0.2
Total	100.0	100.0	100.0	100.0	100.0

[1]Figures are %

Table 5. Adjusted Odds Ratios for Incorrect Self-Screening as Verified by Provider Screen, by Selected Sociodemographic Characteristics

	Respondent's Self-Evaluation of….			
	Hypertension conditions		Presenting one or more contraindications to pill use	
	Incorrectly self-reported hypertension	Incorrectly self-reported **no** hypertension	Incorrectly self-reported contraindication	Incorrectly self-reported eligible for pill use
Age				
≤30	--	--	--	--
30-34	1.905	**2.030****	1.782	1.353
35-39	0.942	**2.692****	0.998	**1.941****
40-44	1.189	**3.386****	0.502	1.724
45-49	1.748	**5.519****	1.206	**2.154****
Primary language used at home				
English	--	--	--	--
Both English and Spanish	0.592	0.665	1.125	0.894
Spanish	2.591	**0.599****	0.687	**0.615****
Education				
Less than high school	--	--	--	--
High school completed	0.492	0.726	0.734	0.827
Some college	0.853	0.990	0.601	1.466
College or higher	0.718	0.909	0.713	1.413
Parity				
Nulliparous	--	--	--	--
One or more	1.258	0.592	0.767	0.682
Contraceptive use				
Hormonal method	--	--	--	--
Non-hormonal method	1.363	0.838	0.668	0.874
None	0.778	0.663	0.571	0.661
Sample size	n=1,355		n=1,335	

** p<.05

§ Comparison group for each of these outcomes is "Respondent's self-assessment for pill use agrees with evaluation by nurse practitioner."