

Over-the-Counter Access, Changing WHO Guidelines, and Contraindicated Oral Contraceptive Use in Mexico

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This study examines the prevalence of contraindications to the use of oral contraceptives in Mexico by sociodemographic characteristics and by whether this family planning method was obtained with or without a doctor's prescription. Using data on smoking behavior and blood-pressure measurements from the 2000 Mexican National Health Survey, the authors found that, under the 1996 World Health Organization (WHO) medical eligibility guidelines, the prevalence of contraindications is low and that no significant differences in contraindications exist at any level between those who obtain oral contraceptives at clinics and those who obtain them at pharmacies. In 2000, however, WHO substantially revised its criteria regarding the level of hypertension that would constitute a contraindication for oral contraceptive use. Applying the new guidelines, the authors found that 10 percent of pill users younger than 35 and 33 percent aged 35 and older have health conditions that are either relative or absolute (Category 3 or 4) contraindications. The relevance of these findings to the larger debate concerning screening and over-the-counter access to oral contraceptives is discussed. (STUDIES IN FAMILY PLANNING 2006; 37[3]: 197–204)

Since their introduction in the 1960s, oral contraceptives (OCs) have become a safe, effective, and popular method of contraception around the world (Grimes 1992). In the United States and many other countries, women must obtain a prescription from a clinician before they can obtain the pill. In addition to screening for medical appropriateness for OC use, women are often required to undergo other examinations, such as Pap smears and breast and pelvic exams, prior to receiving the pill, although the conditions they are screened for are largely unrelated to contraceptive use (Stewart et al. 2001). Women are then required to repeat the process each year to renew their OC prescription. In many less developed countries, however, the pill is available by means of community-based distribution (CBD) programs or at pharmacies without screening or the additional examinations (Bailey et al. 1982; Zavala et al. 1987).

Whether over-the-counter (OTC) or CBD access to oral contraceptives results in use of this method by sub-

stantial numbers of women for whom it is medically contraindicated (FDA 2000), and whether screening for such contraindications is effective and worthwhile are questions that have generated considerable debate during the past four decades (Rosenfield 1971; Rosenfield and Limcharoen 1972; Atkinson et al. 1974; *Family Planning Perspectives* 1975; Huber and Huber 1975; Isaacs 1975). Rosenfield (1971) was one of the first to recognize the impracticality of requiring a medical prescription in rural areas with low physician-to-population ratios and the danger to women in light of the relative risk of maternal morbidity in developing countries. With his advice, in 1969 the Thai government began a pilot program allowing auxiliary midwives to prescribe oral contraceptives (Rosenfield and Limcharoen 1972), which, in turn, led to universal prescriptive rights for midwives using a simple checklist (Rosenfield 1971). In 1973, following upon the Thai study and the growing popularity of OCs worldwide, the International Planned Parenthood Federation's Central Medical Committee released a policy statement on OC distribution, declaring that "the limitation of oral contraceptives to doctors' prescription makes the method geographically, economically and sometimes culturally inaccessible to many women. As a consequence, death and sickness of women and children, which might otherwise be avoided by voluntary limitation of fertility, continue" (Kleinman 1974: 57). This statement became a landmark, guiding the spread of OTC and CBD programs during the subsequent decades.

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Experimental distribution channels were tested throughout Latin America in the 1970s. Early programs focused on access, however, and did not screen women for appropriate use. For example, early initiatives in Brazil, Colombia, and Honduras introduced CBD programs in which women were not screened for contraindications; instead, those experiencing side effects were referred to nearby clinics (Isaacs 1975).

One of the few studies to examine how well women self-screen for contraindications to OC use was conducted in Mexico, where the pill is generally available over the counter (Zavala et al. 1987). Nurses interviewed and checked the blood pressure of OC users obtaining their pills through a CBD network and of those obtaining their pills from other sources, including pharmacies (either with or without a prior consultation with a doctor). The nurses found that most OC users, regardless of whether they had previously consulted a physician, were knowledgeable about whether they had particular health conditions, although they were not necessarily aware that these conditions would constitute contraindications to OC use. Women obtaining their OCs from these different sources had similar health profiles and prevalence of risk factors, suggesting that the women who had been screened by doctors were not significantly healthier. Even among those who reported having been examined by a doctor, 20 percent said they did not have their blood pressure tested, and more than half had not been questioned about chest pains, leg pains, liver problems, or smoking. Another recent study conducted in Mexico also documented the poor quality of medical screening prior to OC use (Tatum et al. 2005).

The authors of the present study were motivated to return to these questions for two reasons. First, several recent studies have called into question the effectiveness of the screening procedures now in place (Becker et al. 2004; Tatum et al. 2005); second, the medical conditions regarded as constituting contraindications recently have been expanded. In 2000, on the basis of new evidence concerning the risk for cardiovascular events among OC users with high blood pressure, the World Health Organization (WHO) substantially revised its criteria regarding the levels of hypertension that determine both a relative and an absolute contraindication for OC use (WHO 2000). Both developments suggest that a substantial number of women may be using the pill who might be better off using another type of contraceptive.

In this report, we examine oral contraceptive use in Mexico, a country where the method is available over the counter in pharmacies and also is supplied through a wide variety of other outlets, with varying degrees of medical supervision. We assess the prevalence of contraindications according to both the old and new criteria, and see how the prevalence of the main contraindi-

cations—hypertension and smoking—vary among OC users according to where they obtain their contraceptives, and how prevalent these conditions are in the general population. Our data are drawn from the 2000 Mexican National Health Survey (ENSA), a large, nationally representative survey that collected data on blood pressure, smoking, and contraceptive use from women aged 20 or older. In examining the relationship between the type of provider and the prevalence of contraindications, we adjust for several indicators of socioeconomic status. We also show how the changes made to the WHO's medical eligibility guidelines between 1996 and 2000 affect the prevalence of contraindications among oral contraceptive users, and we assess the magnitude of the problem that contraindications now represent in this setting.

Data

The 2000 ENSA was designed to estimate the frequency and distribution of health indicators, risk factors, and illness in Mexico. It was further intended to aid in evaluating the national health-care system and to illuminate associations between health and socioeconomic status.

From September 1999 to March 2000, a door-to-door four-stage survey of households was conducted on a probability-proportionate-to-size sample. The population was stratified by urban-rural residence to ensure a sampling proportion that accurately reflected the country's population. Fourteen municipalities from each state were selected based on probability proportionate to size according to the number of households in each municipality. Five AGEBs (census tracts), three blocks from each AGEB, and seven households from each block were selected randomly, according to size, to create the final household sample (Valdespino et al. 2003).

ENSA 2000 consisted of five questionnaires. The first questionnaire was addressed to the head of the household and covered the physical characteristics of the house and socioeconomic and general health questions about each member of the household. The second questionnaire was completed for every member of the household who had used health services in the past year. The final three questionnaires were completed for a randomly selected 0-9-year-old, 10-19-year-old, and an adult aged 20 or older in each household. The adult questionnaire covered risk factors and illness in addition to collecting various biomarkers, including two blood-pressure readings (Valdespino et al. 2003).

The data set is particularly well suited to the current study because of its combination of contraceptive-use data, self-reported risk factors, and a blood-pressure measurement for a nationwide random sample. Because women younger than 20 did not have their blood pres-

sure read and women older than 49 are unlikely to be at risk of becoming pregnant, this analysis is restricted to respondents between the ages of 20 and 49. Pregnant women were excluded from this sample because pregnancy affects blood pressure and (ideally) smoking behavior, our two dependent variables of interest.

Measures

Contraceptive Use

In order to assess contraceptive use and method source, respondents were asked the following questions: "What are you or your partner doing to avoid becoming pregnant?" (¿Qué están haciendo usted o su pareja para no tener hijos?), and "Where did you obtain (the method)?" (¿Dónde consiguió [le pusieron o la operaron]?) The major sources of oral contraceptives in Mexico are public institutions (such as the Mexican Institute of Social Security and the Ministry of Health), nonprofit clinics, private physicians, and pharmacies. For this analysis, all public and private clinics are grouped together because, theoretically, they all conduct some sort of physical examination and screening before providing oral contraceptives. Women currently obtaining their pills from a specific source did not necessarily get their pills first at that source, however. In preliminary analyses based on data from another national survey, the 2003 Mexican National Survey of Reproductive Health, we found that although 95 percent of women who obtain oral contraceptives from public clinics initiated use there as well, 50 percent of those who obtain the pill at a pharmacy first obtained the method from a private doctor or from a nonprofit clinic.

Contraindications

In 1996, the World Health Organization developed a uniform set of medical eligibility criteria for contraceptive use. Its objectives were to create an evidence-based guide for program directors and clinicians worldwide for the provision of contraceptives, to highlight risks associated with certain medical conditions, and to lower barriers to contraceptive use that were based on unproved theory or outdated medical information (WHO 1996). These guidelines were updated in 2000 to reflect new evidence. In particular, the hypertension guideline for combined oral contraceptive (COC)¹ use was tightened, based on new evidence.

The WHO (2000) classifies contraindications for women's contraceptive use according to four categories:

- (1) The client can use the method. No restrictions on use are required.
- (2) The client can use the method. Advantages of using the method generally outweigh its theoretical or proved risks.

- (3) The client should not use the method unless a doctor or nurse makes a clinical judgment that she can use it safely. Theoretical or proved risks usually outweigh the advantages of the method. The method being considered is the method of last choice, for which regular monitoring will be needed.
- (4) The client should not use the method. Her condition represents an unacceptable health risk if the method is used.

According to the 2000 WHO guidelines, the following medical conditions are classified as Category 3 or Category 4 risks for low-dose combined oral contraceptive use: smoking, for women aged 35 and older; elevated blood pressure; past hypertension for which blood pressure cannot be evaluated currently; adequately controlled hypertension, where blood pressure can be monitored; breastfeeding for a period of less than six months postpartum; current or past breast cancer; diabetes with vascular disease or diabetes lasting for more than 20 years; current or past thromboembolic disorder; current or past ischemic heart disease; valvular heart disease with complications; major surgery with prolonged immobilization or surgery on legs; past stroke; migraine headaches for women aged 35 or older or migraines with focal neurological symptoms for women of any age; and active liver disease (WHO 2000).

Our analysis focuses on the most common Category 3 and 4 contraindications and those for which data are available in the ENSA questionnaire: hypertension and smoking.

Hypertension

As Table 1 indicates, the revised 2000 WHO guidelines contained a stricter criterion for hypertension that contraindicated COC use than did the original 1996 guidelines.

The data used in this study were collected in 2000. Consequently, clinicians or health-care workers who may have screened women in the sample for the appropriateness of COC use could only be expected to use the 1996 guidelines, because the newer guidelines had not been published at the time of data collection. Therefore,

Table 1 World Health Organization's medical eligibility criteria for combined oral contraceptives, 1996 and 2000

Blood-pressure level	1996 contraindication category	2000 contraindication category
SBP 140–159 mmHg or DBP 90–99 mmHg	2 if monitored, 3 if not	3
SBP 160–179 mmHg or DBP 100–109 mmHg	3 if monitored, 4 if not	4
SBP ≥180 mmHg or DBP ≥110 mmHg	4	4

SBP = systolic blood pressure. DBP = diastolic blood pressure.

Sources: WHO (1996 and 2000).

we could reasonably expect women with blood pressure of 160 mmHg or higher (systolic) or of 100 mmHg or higher (diastolic) to be screened and restricted from use except in extraordinary circumstances in which use could be closely monitored and no other contraceptive would be appropriate.

For ENSA 2000, two blood-pressure readings were taken by trained interviewers using a manual sphygmomanometer. The first reading was taken after a five-minute rest and the second reading at least five minutes later (Sanchez-Castillo et al. 2005). The mean systolic and mean diastolic measurements were calculated and used for determining contraindication status.² Women were considered to have Category 4 hypertension according to the WHO 2000 guidelines if their mean systolic level was 160 mmHg or higher or if their diastolic level was 100 mmHg or higher. Because this is the same category as the 1996 Category 3 restriction, we could expect that COC use would be contraindicated for these women in most circumstances. As shown in the table, women were considered to have Category 3 hypertension according to the 2000 guidelines if their mean systolic level was between 140 and 159 mmHg or if their diastolic level was between 90 and 99 mmHg.

Smoking

The 1996 and 2000 WHO guidelines for smoking and combined oral contraceptive use are similar. Women aged 35 and older who smoke are restricted (Category 3) from using COCs. Women who smoke more than 15 cigarettes a day (20 cigarettes in 1996) are unconditionally restricted (Category 4) from using COCs (WHO 2000).

ENSA respondents were asked a series of questions about their smoking practices. Questions relevant to this study include “Do you smoke?” (*¿Actualmente fuma?*), “How often do you smoke?” (*¿Con que frecuencia fuma?*), and “On the days that you smoke, how many cigarettes do you smoke?” (*Los días que fuma ¿Cuántos cigarillos consume?*). Women aged 35 and older are classified as smokers (Category 3) if they currently smoke daily or if they currently smoke more than three cigarettes a day when they smoke. Women aged 35 and older are considered heavy smokers (Category 4) if they currently smoke, smoke daily, and smoke more than 15 cigarettes a day, or, if they currently smoke but not daily, they smoke more than 20 cigarettes on the days they smoke.

Socioeconomic Variables

Other variables that are controlled in the multivariate regression include age, education, urban residence (living in a town of more than 15,000 people), speaking the indigenous language, and living in a household with a telephone—a good marker of economic status in Mexico.

Analyses

We use bivariate analyses to explore differences in sociodemographic characteristics and contraindications by provider. Multivariate regressions are used to refine the relationship between OC provider and contraindications, adjusting for differences in sociodemographic characteristics. The first analysis aims to provide an estimate of the prevalence of contraindications for pill use in this population, classified according to women’s current source of contraceptives, as well as a comparison of the prevalence of these same conditions among women who were using other methods or no method. The second analysis provides estimates of the prevalence of contraindications, adjusting not only for pill use by source but also for age and socioeconomic characteristics in order to permit a refined indication for clinicians and users of the amount of screening taking place and to provide insight into how hypertension and smoking vary according to basic social and demographic groups in this highly stratified society.

All analyses were performed using Stata 9 computer software, and all take into account the sampling methods employed in ENSA.

Results

Six percent (1,246) of the 21,080 nonpregnant women aged 20–49 in the ENSA 2000 sample report that they currently use oral contraceptives for birth control. Forty percent (501) of these women obtain their pills from pharmacies, whereas 56 percent (694) obtain their pills from a health clinic of some sort (see Table 2). Four percent (51) of pill users are excluded from the analyses because their provider is unknown.

Table 3 presents the characteristics of women surveyed, divided into three categories: OC users who obtain their pills at pharmacies, OC users who obtain their pills from clinics, and the nonpregnant female population who are not using this method. Important composi-

Table 2 Percentage of women surveyed who reported using oral contraceptives (n = 1,246), by method provider, ENSA 2000

Provider	Percent
Clinic	
Mexican Institute of Social Security	11.5
Ministry of Health	33.3
Other public health institution	5.5
Private doctor/NGO	5.5
Pharmacy	40.1
Unknown/“other” (excluded)	4.1

ENSA = Mexican National Health Survey.

Table 3 Percentage of women surveyed, by selected sociodemographic characteristics, according to oral contraceptive use and provider, Mexico, 2000

Characteristic	Users/pharmacy	Users/clinic	Nonusers
Age			
20–24	22.6	28.2	24.0
25–29	25.9	28.8	19.6
30–34	23.0	18.9	17.7
35–39	16.0	13.9	16.0
40–49	12.6	10.2	22.9
Education			
<Complete primary	13.5	26.5	21.9
Complete primary	20.9	28.5	23.3
Some secondary	24.1	26.2	24.4
Secondary+	41.5	18.8	30.5
Socioeconomic status			
Household owns a telephone	50.9	19.9	36.7
Marital status			
Single	8.6	1.8	21.2
Cohabiting	13.9	27.5	16.9
Married	75.4	69.7	55.5
Divorced/widowed	2.1	1.0	6.4
Residence			
Urban (≥15,000 residents)	75.9	44.0	63.4
Rural (<15,000 residents)	24.1	56.0	36.6
Ethnicity			
Speaks indigenous language	1.0	8.7	6.6
(N)	(501)	(694)	(19,834)

tional differences are found among these groups. Not only are women who use the pill different from nonusers, but also women who obtain their pills at pharmacies are markedly different from women who get them at clinics.

Prevalence of Contraindications

Table 4 presents the prevalence of specific contraindications to COC use according to various medical guidelines. The variable “contraindicated” refers to women for whom OC use would be contraindicated based on their blood-pressure level or smoking behavior. The first segment refers to women for whom, at the time of the survey and according to the criteria relevant at that time, OC use would be contraindicated at least at the Category 3 level. In other words, these are women who should have been screened for pill use and given an alternative form of contraception except in extraordinary circumstances where regular monitoring would be possible. The Category 3 designation refers to women who fall at least within the Category 3 boundaries but who may also meet the Category 4 absolute prohibition against COC use.

The second and third segments of Table 4 refer to women for whom OC use would be considered relatively and absolutely contraindicated, respectively, according to the revised WHO criteria.

Table 4 Percentage of women surveyed, by contraindications for oral contraceptive use, according to age, user status, and provider, Mexico, 2000

Health condition/ contraindication	Age	Users/ pharmacy	Users/ clinic	Non- users	
1996 Category 3					
Hypertension (≥160/100 mmHg)	Total	1.7	1.8*	3.3	
	<35	1.2	1.1	1.3	
	≥35	3.1	4.2	6.4	
Smoking	≥35	9.4	7.5	9.9	
	Contraindicated	Total	4.5*	3.6*	7.1
		<35	1.2	1.1	1.3
≥35		12.8	11.6	16.0	
2000 Category 3					
Hypertension (≥140/90 mmHg)	Total	15.4	15.8	17.2	
	<35	9.5	13.0	10.8	
	≥35	30.3	24.7	27.2	
Smoking	≥35	9.4	7.5	9.9	
	Contraindicated	Total	17.8	17.4	20.2
		<35	9.5	13.0	10.8
≥35		38.6	31.3	34.8	
2000 Category 4					
Hypertension (≥160/100 mmHg)	Total	1.7	1.8*	3.3	
	<35	1.2	1.1	1.3	
	≥35	3.1	4.2	6.4	
Heavy smoking (≥15 cigarettes/day)	≥35	0.9	0.0	1.1	
	Contraindicated	Total	2.0	1.8*	3.8
<35		1.2	1.1	1.3	
≥35		4.1	4.2	7.5	
(N)		(501)	(694)	(19,834)	

*Difference from nonusers significant at $p < 0.05$.

Despite the potential for professional screening in clinics, no significant differences can be observed in contraindications at any level between OC users who obtain their pills at a clinic and those who purchase them at a pharmacy. Differences between OC users and nonusers are clear, however. Three findings are of particular interest. First, levels of contraindications at the 1996 Category 3 level—the level at which providers could have been expected to screen at the time of the survey—are low for both pharmacy customers and clinic clients, particularly for those younger than 35, for whom only 1 percent show a relative contraindication to use.

Second, prevalence of hypertension (160/100 mmHg or higher) is reduced for oral contraceptive users compared with nonusers (although this difference is not statistically significant for users who buy their pills at a pharmacy). Most of these differences are driven by differences in hypertension levels among women older than 35.

Third, when the new medical eligibility guidelines (2000 Category 3) are applied, a marked increase is seen in the prevalence of contraindications. One-sixth of all pill users and one-third of older pill users would be cautioned against pill use by the World Health Organization in a setting where access to clinical judgment was limited. Few pill users meet the 2000 Category 4 criteria

for absolute prohibition of OC use; nonetheless, for 2 percent of women and 4 percent of women aged 35 and older who are using the pill, the method represents an “unacceptable health risk” (WHO 2000:8).

Predictors of Contraindications

The differences in socioeconomic characteristics and age profile seen in Table 3 can be expected to influence the levels of contraindications seen in Table 4. Moreover, the association between these characteristics and contraindications may be expected to vary according to the contraindication being considered. For example, high blood pressure usually is associated negatively with level of educational attainment (Dyer et al. 1976; Liu et al. 1982; Stamler et al. 1991), whereas smoking is still, to some extent, associated positively with educational level in Mexico. In order to separate the effect of sociodemographic differences from the possible effect of contraceptive provision, three multivariate models were run using selected contraindications to OC use as the dependent variables (see Table 5).

With respect to smoking among older women, Model 1 in Table 5 shows that the educated are more likely to smoke than the uneducated. An inverted U trend is indicated, with smoking peaking among women having some

secondary education before declining among those with higher education. Urban residence, not being indigenous, and phone ownership are positively associated with smoking. After controlling for socioeconomic factors, a noticeable but nonsignificant reduction in smoking remains among OC users older than 35 who purchase their pills at a pharmacy, but little effect is found among users who obtain their method at a clinic. The negative association with pill use appears to be stronger with respect to heavy smoking (not shown). Indeed, no users who were clinic clients in this sample reported being heavy smokers.

The regression results show that hypertension increases with age and decreases with education and phone ownership. Under the more liberal 1996 blood-pressure criteria (Model 2) there is a nonsignificant reduction in elevated blood pressure among both users who obtain their pills at a clinic and those who buy them at a pharmacy. For the more conservative 2000 blood-pressure criteria (Model 3), no difference is seen in high blood pressure although the other predictors in the model stay the same.

Discussion

The ENSA is one of few surveys that permit an assessment of the prevalence of the two most important contraindications for oral contraceptive use with a large nationally representative sample. The main questions we seek to address with these data concern the prevalence of contraindications, the degree to which women who use oral contraceptives are screened for these contraindications, and whether screening differs between clinic clients and pharmacy customers. The answer to the first question turns out to be highly sensitive to how the contraindication for hypertension is defined. A considerable difference is observable between the proportion of women with contraindications resulting from hypertension as based on the 1996 Category 3 WHO guidelines and that which results from applying the revised (2000 Category 3) WHO guidelines. By the 1996 criteria, this method is contraindicated for only a small proportion of OC users (about 4 percent), and the largest share of those with contraindications is accounted for by women aged 35 and older who smoke. Using the 2000 criteria increases the share of users for whom OC use would be contraindicated to almost 18 percent, a proportion that is virtually identical among users who obtain OCs at a pharmacy and those who obtain them at a clinic. Moreover, hypertension accounts for the large majority of contraindications, even among women older than 35, when the 2000 criteria are used.

The prevalence of women with contraindications for OC use based on the 1996 WHO criteria is significantly lower among pill users than it is in the general popula-

Table 5 Adjusted odds ratios for selected contraindications for combined oral contraceptive use, by selected sociodemographic characteristics, Mexico

Characteristic	Model 1	Model 2 (1996 WHO criteria)	Model 3 (2000 WHO criteria)
	Some smoking ≥35 years of age	Hypertension (≥160/100 mmHg)	Hypertension (≥140/90 mmHg)
Age			
20–29	—	0.29**	0.44**
30–34	—	0.54**	0.64**
35–39 (r)	1.00	1.00	1.00
40–49	1.23	2.20**	1.77**
Education			
<Complete primary (r)	1.00	1.00	1.00
Complete primary	1.73**	0.70*	0.87
Some secondary	2.48**	0.66*	0.71**
Secondary+	2.02**	0.64**	0.62**
Residence			
Rural (<15,000 residents) (r)	1.00	1.00	1.00
Urban (≥15,000 residents)	2.27**	0.97	0.98
Ethnicity			
Nonindigenous (r)	1.00	1.00	1.00
Indigenous	0.20**	0.81	0.83
Socioeconomic status			
No phone in household (r)	1.00	1.00	1.00
Phone in household	1.54**	0.82	0.91
Oral contraceptive use status/provider			
Nonuser (r)	1.00	1.00	1.00
User/pharmacy	0.80	0.67	1.07
User/clinic	0.95	0.74	1.11

— = Not applicable. (r) = Reference category. *Difference significant at $p < 0.05$; ** $p < 0.01$.

tion, suggesting that considerable screening using the older criteria is taking place. Among pill users, once we adjust for the effects of age, education, residence, ethnicity, and socioeconomic status, OC use is still less likely to be contraindicated, although this finding is not statistically significant. Perhaps of greatest policy interest, however, is that no significant differences in contraindications are found at any level considered in this study between users who obtain OCs at clinics and those who obtain them at a pharmacy. An ancillary conclusion is that when large socioeconomic differentials are found among users according to method source, adjusting for the relevant characteristics is imperative, because they are strongly correlated with both smoking and hypertension in a setting such as Mexico, albeit in opposite (and offsetting) directions. Finally, although this study provides no indication that over-the-counter access to the pill results in a substantial proportion of women who are using a method contraindicated for them, just how and when the screening of this population occurs is not clear. As noted earlier, in Mexico the original source of a contraceptive is frequently not the same as the regular source, and women who are classified as buying the pill at a pharmacy because that is their current source may have had an initial screening for pill use from either a private- or public-sector doctor. Therefore, we cannot distinguish reliably between self-screening and that carried out by a provider.

The measures available to us from ENSA 2000 are subject to additional limitations. A diagnosis of hypertension is made, ideally, after two or more blood-pressure readings are taken on different occasions (Lloyd-Jones et al. 1999). Blood-pressure measurements are also potentially susceptible to so-called white-coat hypertension, that is, blood pressure elevated because of anxiety induced by the interview rather than as the result of a health condition. Additionally, blood pressure can increase slightly as a result of oral contraceptive use, and, therefore, some hypertensive women in the sample may have had normal blood-pressure levels at the time they began using the method and were in fact appropriately screened. Furthermore, our analysis is based on the assumption that all OC users in the sample are using low-dose combined oral contraceptives. Although this version of the pill accounts for nearly all pill use in Mexico, a small proportion of users may take progestin-only oral contraceptives, for which smoking and hypertension are not contraindications.

What should be made of our finding that about one-sixth of women who were using the pill in the year 2000 would appear to be contraindicated for this method according to the revised WHO guidelines that appeared in that same year? Of course, these guidelines could not have influenced or oriented medical counseling or wom-

en's own decisions regarding method choice before they were issued. Indeed, the corresponding changes in the Mexican government's guidelines were not formally approved until January 2004 (Secretaría de Salud 2004). Nevertheless, our finding provides a useful benchmark concerning the number and proportion of women who, presumably, would need to be counseled or informed of the possible health consequences of their continued use of this method and about alternative methods that they might consider using.

Given that combined oral contraceptives account for only a relatively small proportion of contraceptive use in Mexico, especially among older women who are the most likely to suffer from hypertension, the challenge posed should be manageable. Some of the necessary switching of methods may have taken place already. One of the major public providers, the Mexican Institute of Social Security, is now prescribing progestin-only oral contraceptives to women older than 35. Moreover, both public and private providers may have adopted the new criteria already when counseling women regarding either the initiation or continuation of a contraceptive method. Because the combined pill formula is available over the counter, however, a campaign or other means of communication designed to provide all women with information regarding hypertension and pill use clearly is warranted.

In other countries, implementing the revised WHO criteria could present more challenges, however. In settings where resources are scarce and where access to other methods of contraception is limited, the risk of unintended pregnancy and its associated hazards of unsafe abortion and maternal mortality might outweigh the risks of contraindicated oral contraceptive use. Allowing for contraindicated OC use may be particularly important in light of a recent review that found hypertensive disorders to be the leading cause of maternal mortality in Latin America and the Caribbean (resulting in 26 percent of maternal deaths) (Khan et al. 2006). Clearly, in designing policy, the implications of denying women access to oral contraceptives because of hypertension must be considered carefully if an unintended pregnancy would place them at greater risk. In addition, in countries where combined oral contraceptives constitute a much larger proportion of the method mix, such as Bangladesh, Brazil, and Morocco, the proportion of all contraceptive users who should be advised to switch methods in order to comply with the new WHO guidelines might be much greater than in Mexico. In such cases, the task of identifying users with contraindications and finding alternative methods for them would constitute a correspondingly larger challenge.

The results presented here show that the incidence of hypertension reflects a strong socioeconomic gradient in the Mexican setting, but much remains to be learned

about the prevalence of hypertension among COC users in other settings and across social, demographic, and ethnic groups. Including instruments or procedures for the diagnosis of hypertension in nationally representative samples that collect information on contraceptive use would be useful. Moreover, in addition to providing information relevant to the amount of method switching that might be advisable, such studies also have the potential to shed light on the effectiveness of screening in different contexts and how that is related to the institutional circumstances governing the provision of hormonal contraception. Although the latter is an old question, it has gained renewed relevance as a result of the substantial change in the scientific consensus regarding contraindications included in the new WHO guidelines.

Notes

- 1 Combined oral contraceptives (COCs) refer to pills that contain both estrogen and progestin, in contrast to progestin-only pills. The vast majority of pills used in Mexico and worldwide are COCs.
- 2 Using the mean measurements increases the consistency of the blood-pressure reading. See Lloyd-Jones et al. (1999) for an example of this technique.

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