

# Physician Attitudes Toward Over the Counter Availability for Oral Contraceptives

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**Abstract** To assess physician attitude towards making oral contraceptives available over the counter in the United States (US). We assessed physician attitudes towards a transition from prescription only to over-the-counter availability (rx-OTC) for oral contraceptive pills by disseminating an electronic survey directed primarily to residents training in Obstetrics and Gynecology (OBGYN) and Family Practice in the US. An overwhelming majority of 638 respondents (71 %) were against an rx-OTC switch for combined oral contraceptives and among this subset of respondents the primary concern was safety (92.3 %). Overall, respondents were evenly divided on the issue of an rx-OTC switch for progestin-only-pills but of those who opposed, 73.2 % cited safety as their primary concern. For progestin-only-pills female respondents were more likely to support OTC availability. Most OBGYN and Family Practice residents opposed to OTC availability for oral contraceptives cite safety as their primary concern. Considering the abundant evidence as to the overall safety of oral contraceptives, especially progestin-only-pills, there appears to be a knowledge deficit among OBGYN and Family Practice residents regarding the safety of oral contraceptives.

**Keywords** Oral contraceptives · OBGYN resident · Over-the-counter · Rx-OTC

## Introduction

In America there continues to be a high rate of undesired pregnancy and contraception non-use, particularly among women of low socio-economic status and among adolescents [1–3]. Access to contraception continues to be at risk for women and recent public policy decisions have served to re-surface this issue.

As part of the new Patient Protection and Affordable Care Act [PPACA] (Public Law 111–8 148), the government of the United States required that even religiously affiliated organizations must include contraceptive coverage with no co-pay in their health insurance plans. This resulted in enormous controversy and renewed an intense national debate on access to contraception.

The persistently high rate of unintended pregnancy in the US and the popularity of the oral method of contraception have led to renewed calls for over-the-counter (OTC) availability for oral contraceptives. As classified by the Federal Drug Administration (FDA), OTC drugs have the following characteristics: their benefits outweigh their risks, their potential for misuse and abuse is low, the consumer can use them for self-diagnosed conditions, they can be adequately labeled by the manufacturer and health practitioners are not needed for safe and effective use. No true “behind-the-counter” designation exists in the US but this term refers to drugs which have OTC status but with certain restrictions on their sale including minimum age of purchase and proof of identity. As an example, the levonorgestrel emergency contraceptive (Plan B) has OTC access only for those aged 17 years and older and must be

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sold from a licensed pharmacy. The American College of Clinical Pharmacy recently published an opinion statement calling for OTC availability for oral contraceptives under two conditions: that they are sold where a pharmacist is on duty and that there are mechanisms in place to cover OTC contraceptives through Medicaid [4]. They argued that existing data indicate that oral contraceptives meet safety criteria required of OTC products, that women can self-screen for contraindications to oral contraceptives [5] and, importantly, that experience with OTC emergency contraception suggests that OTC oral contraceptives would not increase sexual risk-taking behavior [6, 7].

A 2004 U.S. national telephone survey of 811 women aged 18–44 years examined their readiness and comfort level of obtaining oral contraceptives, the ring, the patch, or emergency contraceptives directly from the pharmacist without a prior prescription [8]. When asked about pharmacy access to contraceptives, 76 % of women reported they would personally benefit if a clinic visit was not required before filling their prescription, with 68 % of women saying they would use pharmacy access to obtain hormonal contraception if available. The above studies indicate where women and pharmacists stand on the issue of OTC availability for oral contraception but missing from the literature was any comparable large scale survey of physician attitudes towards an rx-OTC transition for oral contraceptives. This was the motivation behind our study.

Knowing that OBGYN physicians and Family Practice physicians are the primary prescribers of oral contraceptives we sought to ascertain the attitudes primarily of resident physicians in these fields towards an rx-OTC transition for both combined oral contraceptives and progestin-only-pills.

## Materials and Methods

### Study Design and Oversight

We conducted an anonymous Internet based electronic survey of trainees in Obstetrics and Gynecology within the United States. We used Survey Monkey to create and disseminate the survey. We compiled a list of every OBGYN and Family Practice residency program along with the contact information for the program coordinator. Then, we emailed the program coordinator for each program informing them of the survey and asking them to forward the link to their residents via their program wide email list. Reminder emails were sent out every 2–4 weeks over a 6 month period. This study was reviewed by the Institutional board at the Saint Luke's Hospital in Kansas City, Missouri and was deemed to meet the criteria for being exempt from committee review. Although the target population was

resident physicians training in OBGYN and Family Practice, we expected that a small number of attendings, fellows and other staff would receive and complete the survey since they are sometimes included on emails sent to residents. Our *a priori* plan was to include these responses and, if large enough in number, conduct separate analyses.

### Survey Design

The actual survey is shown in Table 1. The first and third questions asked whether progestin-only-pills and combined oral contraceptive pills, respectively, should be available over the counter in pharmacies and local drug stores in the United States. We did not distinguish between “behind-the-counter” and “over-the-counter” in our survey since there is technically no true behind-the-counter designation that exists in the US. The survey was designed in a way that respondents were required to give an answer to these questions and could not skip them. If respondents answered ‘no’ to either question they were then required to answer the second and or fourth question regarding their top concern. The electronic survey was also designed such that all of the remaining six questions could not be skipped. By designing the survey in this manner we ensured that there were no missing data.

### Study Hypotheses

We hypothesized that a statistical majority of respondents (who we expected to be comprised of predominantly OBGYN and Family Practice residents) would be against making the rx-OTC switch for combined oral contraceptive pills. We also hypothesized that a statistical majority of respondents would be against an rx-OTC switch even for progestin-only-pills. Finally, we hypothesized that there would be no association between physician characteristics (gender, region of practice, specialty, type of practice) and attitude towards an rx-OTC switch for oral contraceptive pills.

### Statistical Analysis

For the two primary research questions in the survey we compared the proportion of respondents against an rx-OTC transition to the null value of 0.5 using the one-sample binomial probability test. Because our hypothesis was that a majority of respondents would be against an rx-OTC transition for oral contraceptives, we used 1-sided *p* values in evaluating statistical significance. We assessed the association between physician characteristics and attitude towards an rx-OTC transition for oral contraceptives using the Chi square test of association. Since our hypothesis was that there would be no association between physician

**Table 1** Survey design

1. Should *progesterone only* oral contraceptive pills (such as micronor) be available over the counter in pharmacies and local drug stores in the United States?  
1 = Yes 2 = No
2. If you answer is 'no', what is your top concern?  
1. Safety 2. Loss of income (now that women would no longer have to pay for an office visit) 3. It would encourage even more casual sex (putting women at higher risk for STDs) 4. None of the above
3. Should combined oral contraceptive pills (*containing both estrogen and progesterone*) be available over the counter in pharmacies and local drug stores?  
1 = Yes. 2 = No
4. If not, what is your top concern?  
1. Safety. 2. Loss of income (now that women would no longer have to pay for an office visit). 3. It would encourage even more casual sex (putting women at higher risk for STDs). 4. None of the above
5. What is your current specialty?  
1. OBGYN. 2. Family practice. 3. Internal medicine. 4. Women's health nurse practitioner (WHNP). 5. Other
6. What is your current level of training?  
1. Attending. 2. Fellow. 3. Resident. 4. Nurse practitioner/midwife. 5. Physician assistant
7. At what type of institution do you practice?  
1. Academic teaching hospital. 2. Private hospital/private practice clinic. 3. Public hospital. 4. Military facility  
5. Other
8. In what region of the country do you see most of your patients?  
1. West. 2. Northeast. 3. South. 4. Midwest. 5. Mountain states
9. How many years has it been since you received your MD (or NP or PA degree)?  
1. <5 years  
2. 5–10 years  
3. 11–15 years  
4. 16–20 years  
4. Greater than 20 years
10. What is your gender?  
1. Female. 2. Male

characteristics and attitudes towards an rx-OTC transition for oral contraceptives, we used two-sided  $p$  values in evaluating statistical significance.

#### Power Calculations

We calculated that at a 2-sided confidence interval of 95 % ( $\alpha = 0.025$ ) we would need at least 320 responses to achieve 90 % power to detect a difference of 10 % points between the proportion of respondents answering "no" to the primary research questions and chance (0.50) [9].

## Results

#### Survey Response Rate

Our survey was completed by 638 respondents, 51.7 % of whom were OBGYN physicians and 45.3 % of whom were Family Practice physicians. Based on the size of the total

population of residents in Family Practice and OBGYN (approximately 15,000), our survey response rate was low (4 %). However, our absolute sample size far exceeded that required by our pre-study power calculations.

#### Characteristics of Survey Respondents

Consistent with the aim of this study, the overwhelming majority ( $N = 574$ , 90 %) of the study respondents were residents. The remaining respondents were attendings (8.2 %), fellows (1.3 %) or Nurse practitioners (0.6 %). Also, not surprisingly, consistent with the make-up of the general body of OBGYN and Family Practice residency programs, 75.1 % of our respondents were female ( $N = 479$ ). In terms of geography 36.5 % of our respondents were currently training in the Midwest ( $N = 233$ ) with 22.6 % ( $N = 144$ ) and 24 % ( $N = 153$ ) currently training/practicing in northeastern and southern states respectively. Of the four major geographic regions the western states accounted for the lowest proportion

(11.3 %) of our respondents. Finally, and also not surprising given that our target population was the population of residents in OBGYN and Family Practice, 76.3 % of our respondents (N = 487) were currently practicing/training in academic teaching hospitals.

### Study Hypotheses

Consistent with our hypothesis, a statistical majority (71 %) of respondents stated that combined oral contraceptives should not be made available over the counter ( $p < 0.001$ ). Of those opposed to OTC availability for combined oral contraceptives, 92.3 % cited safety as their primary concern. With respect to making progestin-only-pills available over the counter, 52.2 % were against and 47.8 % in favor ( $p = 0.14$ ). Of those opposed to OTC availability for progestin-only-pills, 73.2 % cited safety as their primary concern. There was no association between physician geography and attitude towards making either combined or progestin-only-pills available over the counter (Table 2). There was, however, a significant association between respondent gender and attitude towards an rx-OTC switch for progestin-only-pills with female physicians being more likely than their male counterparts to favor OTC availability (Table 2).

### Discussion

To our knowledge this is the first large-scale survey of physicians regarding their views on over the counter availability of oral contraception in the United States. A significant majority of our respondents (primarily OBGYN and Family practice resident physicians) would not be in favor of combined oral contraceptives being available over the counter. On the issue of progestin-only-pills, our respondents were evenly divided for and against an rx-OTC transition. In our study, the driving factor behind physician attitude towards OTC availability for oral contraceptives (for ongoing as opposed to emergency contraception) was concerns regarding safety.

We found in our study that, despite progestin-only-pills having almost no contraindications [10, 11], half of our physician respondents were against even these being available over the counter. This was true not only for our 574 resident physician respondents but also for the 52 respondents that were attendings. Even more puzzling was the fact that over 70 % of those against an rx-OTC transition for progestin-only-pills cited safety as their primary concern. It is possible that those respondents who cited safety as their concern were not really expressing concern over the actual safety of progestin-only-pills but rather were expressing concern over the very concept of women

making contraceptive decisions without first consulting a physician. Another possible explanation is that US residents are not sufficiently educated about the safety of progestin-only-pills.

The results of this study serve to highlight a major gap in perception between pharmacists and physicians regarding the safety of oral contraceptives for OTC availability. The results of this study suggest a potentially important role for physician education regarding the safety criteria for OTC products. Future studies could attempt to develop a teaching tool for physicians regarding the safety requirements for OTC products and then subsequently assess whether this changed physician attitude towards OTC availability for oral contraceptives.

One issue that our survey did not address in detail is the issue of physicians fearing loss of control if women are able to purchase oral contraceptives without a prescription. It is well known that historically physicians in the US would tie compliance with annual screening (for cervical and breast cancer) to receipt of a prescription for oral contraceptives. It is certainly possible that the respondents opposed to OTC availability for oral contraceptives fear that women will be less compliant with their annual health screening if they can directly access oral contraceptives without going through a physician. Available evidence does not support this fear. In a 2004 survey of 811 women in the US, 88 % of women not using contraception in the last 2 years had still obtained a Pap test indicating that even if women are not seeking contraception they will still obtain recommended preventive care [8]. Future studies on the issue of physician attitudes towards OTC availability for oral contraceptives should attempt to incorporate a more comprehensive and in-depth interview of a subgroup of respondents to examine the perception of loss of control among physicians who prescribe oral contraceptives.

One potential and important unintended consequence of OTC status for oral contraceptives is that out-of-pocket costs could increase. It is unclear whether private insurance or Medicaid would cover oral contraceptives with OTC status. In an opinion statement, the American College of Clinical Pharmacy specifically listed Medicaid coverage as one of the conditions under which they would support OTC availability for oral contraceptives.

An important limitation of our survey was that we did not distinguish “over-the counter” from “behind-the-counter.” Although there is no true behind-the-counter designation in the US, some drugs with OTC status have restrictions and this essentially creates a de-facto behind-the-counter category. Drugs with OTC status but which have restrictions are not available “on-the-shelf.” These drugs are dispensed by the pharmacist whose job is to screen the patient for eligibility. Because patients must go through the licensed pharmacist before accessing these

**Table 2** Attitude towards over-the-counter availability for oral contraceptives by physician characteristics

Question	Response N (%)		p value	If no, what is your top concern? N (%)			
	Yes	No		Safety	Loss of income	It would encourage more casual sex	None of the above
Should <i>progesterone only</i> oral contraceptive pills (such as micronor) be available over the counter in pharmacies and local drug stores in the United States? (overall population)	305 (47.8)	333 (52.2)	0.14	243 (73.2)	1 (0.30)	20 (6.0)	68 (20.5)
Region <sup>a</sup>			0.25				
West	40 (55.6)	32 (44.4)					
Northeast	73 (50.7)	71 (49.3)					
South	69 (45.1)	84 (54.9)					
Midwest	102 (43.8)	131 (56.2)					
Gender			0.03				
Male	64 (40.3)	95 (59.8)					
Female	241 (50.3)	238 (49.7)					
Specialty			0.09				
Obstetrics and gynecology	171 (51.8)	159 (48.2)					
Family practice	127 (43.9)	162 (56.1)					
Other	7 (36.8)	12 (63.2)					
Training level			0.95				
Attending	26 (50)	26 (50)					
Resident	273 (47.6)	301 (52.4)					
Other	6 (50)	6 (50)					
Type of institution			0.14				
Academic teaching hospital	241 (49.5)	246 (50.5)					
Other	64 (42.4)	87 (57.6)					
Should combined oral contraceptive pills ( <i>containing both estrogen and progesterone</i> ) be available over the counter in pharmacies and local drug stores? (overall population)	185 (29.0)	453 (71.0)	0.001	418 (92.7)	1 (0.22)	14 (3.1)	18 (4.0)
Region <sup>a</sup>			0.19				
West	27 (37.5)	45 (62.5)					
Northeast	47 (32.6)	97 (67.4)					
South	42 (27.5)	111 (72.5)					
Midwest	60 (25.8)	173 (74.3)					
Gender			0.55				
Male	43 (27.0)	116 (73.0)					
Female	142 (29.7)	337 (70.3)					
Specialty			0.91				
Obstetrics and gynecology	171 (51.8)	159 (48.2)					
Family practice	127 (43.9)	162 (56.1)					
Other	7 (36.8)	12 (63.2)					
Training level			0.20				
Attending	20 (38.5)	32 (61.5)					
Resident	163 (28.4)	411 (71.6)					
Other	2 (16.7)	10 (83.3)					
Type of institution			0.18				
Academic teaching hospital	148 (30.4)	339 (69.6)					

Table 2 continued

Question	Response N (%)		p value	If no, what is your top concern? N (%)			
	Yes	No		Safety	Loss of income	It would encourage more casual sex	None of the above
Other	37 (24.5)	114 (75.5)					

<sup>a</sup> Data for mountain states not shown

drugs there is an opportunity for formal screening for contraindications. It is possible that some of the physicians opposed to “over-the-counter” availability for oral contraceptives, most of whom cited safety as their main concern, would have supported “behind-the-counter” availability. The ability of women and pharmacists to screen for contraindications to oral contraception is a critical component of an rx-OTC transition. Using data from the 2000 Mexican National Health survey researchers found that Mexican women who obtained oral contraceptives over the counter in pharmacies were no more likely to have contraindications than women who obtained them at clinics [12]. However, in another study, among a cohort of 1015 women along the El Paso-Mexico border, relative contraindications (particularly hypertension) were more common among over the counter users in Mexico relative to family planning clinic users in El Paso [13]. In another important study among women in El Paso, Texas, self screening for contraindications to oral contraception with the aid of a medical checklist was found to be very accurate with a sensitivity and specificity of 83 and 88 % respectively [5]. Overall, there is evidence that women can self-screen for contraindications to oral contraceptives should there be a switch to OTC availability.

The most fundamental limitation of this study was that it was a survey. Surveys tend to be completed by individuals with strong feelings regarding the issue being examined and there is always a risk with a survey that the respondents are not truly a representative sample of the target population. Also of note, the survey used in this study had not been previously validated. The low response rate is another point of concern with only 574 OBGYN and Family Practice residents combined out of potentially up to 15,000 responding. Residents are typically saturated with group-wide emails daily including emails soliciting their participation in surveys. It is very easy for residents to ignore mass emails as they quickly scan through their email during their busy days in the hospital. This is likely the chief reason for the low response rate. Also, unlike other resident surveys where the residents are identified and individually contacted (by mail or email) [14] or resident surveys administered immediately after in-training examinations [15], we relied on a completely anonymous and indirect

approach whereby we sent an email to each OBGYN residency program administrator and then depended on them to forward that email to their residents. Because of this completely anonymous and indirect approach we could not target non-responders individually with additional emails asking them to respond and neither did we have the luxury of a captive audience such as residents undergoing a national in-training examination. Also, in this study we did not offer financial incentives as some surveys do to increase the response rate. On the other hand, the absolute size of our study population (638) far exceeded that required based on our power calculations.

In conclusion, this study provides valuable initial insight into the attitude of physicians currently training in Obstetrics and Gynecology and Family Practice towards OTC availability for oral contraceptives. Those opposed to OTC availability for oral contraceptives overwhelmingly cite safety as their primary concern.

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**Conflict of interest** The authors report no conflict of interest.

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