International Journal of Medicine and Pharmacy
June 2015, Vol. 3, No. 1, pp. 5-16
ISSN 2372-5087 (Print) 2372-5095 (Online)

Published by American Research Institute for Policy Development
DOI: 10.15640/ijmp.v3n1a2
URL: http://dx.doi.org/10.15640/ijmp.v3n1a2

Pharmacists' Attitudes towards Three Models of Expanded Access to Hormonal Contraception in Pharmacies

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Abstract

The objectives of this study were to survey pharmacists about their attitudes to three models for expanding access to several types of hormonal contraceptives, their confidence in screening for contraindications to hormonal contraception, and their confidence in patients' self-screening for contraindications to hormonal contraceptives. Surveys were distributed to 52 pharmacists to assess agreement or disagreement about three expanded access models for different forms of hormonal contraception and confidence of screening. The response rate of the survey was 63%. About 54% of the pharmacists did not support pharmacist-prescribed hormonal contraception, although about 60% agreed that they could properly screen for contraindications. About 71% did not support behind-the-counter access and about 95% did not support over-the-counter access to hormonal contraceptives. Over 80% of the pharmacists did not agree that patients could properly self-screen for contraindications. Pharmacists did not show any increased support for extending access to progestin-only contraceptives compared to estrogen-containing contraceptives. The majority of the pharmacists did not support any of the expanded access models for the different forms of hormonal contraceptives and did not show increased support for progestin-only contraceptives. This is the first paper to compare pharmacists' attitudes about these three models for expanding access to hormonal contraceptives.

Keywords: pharmacy access, behind the counter, over the counter, contraceptives, confidence

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1.0 Introduction

1.1 Hormonal contraception is a valuable and popular method for preventing unintended pregnancies throughout the world. Thirty-five countries allow access to some forms of hormonal contraception without a prescription and without screening by a health professional (Grindlay et al, 2013). This type of access to hormonal contraception is not available in the United States (US), even though the American College of Obstetricians and Gynecologists and the Women's Health Practice and Research Network of the American College of Clinical Pharmacy have issued formal statements of support for moving some forms of hormonal contraception to an over-the-counter (OTC) status (Committee on Gynecologic Practice, 2013; McIntosh et al, 2011). Additionally,62%of US women at risk of an unintended pregnancy, and 81% of US women who have experienced an unintended pregnancy support the availability of OTC hormonal contraceptives (Grossman et al, 2013, Grindlay et al, 2014). All forms of hormonal contraception in the US are initiated by a licensed prescriber which does not include pharmacists, unless the state has a pharmacy access law that allows pharmacists to prescribe and/or directly dispense hormonal contraceptives on a recurring basis (Grindlay et al, 2013, Farris et al, 2010).

1.2 One notable exception in the US is the increased access that has been granted to emergency hormonal contraceptives containing the progestin levonorgestrel (LNG). Until 2006, this form of emergency contraception was only initiated by a licensed prescriber for all states or via a pharmacist-initiated prescription for states with pharmacy access laws (Gross et al, 2013).In 2006, theUS Food and Drug Administration (FDA) approved females 18 years of age or older with proof of age to be able to purchase LNG at a pharmacy without a prescription for use as an emergency contraceptive (US Food and Drug Administration, 2006).This restricted non-prescription status is often referred to as behind-the-counter (BTC) (Pray et al, 2011). The access was further expanded in 2009 to females 17 years of age or older, and expanded again in 2013 when the FDA approved a name-brand form of LNG as an over-the-counter (OTC) emergency contraceptive drug without age restrictions or identification requirements (US Food and Drug Administration, 2013).

1.3 There are no other forms of hormonal contraception that have BTC or OTC status in the US. The hormonal contraceptives that are most commonly dispensed by pharmacists in the US include combined oral contraceptive pills (COCs), progestin-only pills (POPs), the transdermal patch OrthoEvra™ (patch), and the intravaginal ring Nuva Ring™ (ring). The hormonal contraceptives administered or inserted by physicians in the US include the hormonal intrauterine device Mirena™ or Skyla™ (LNG-IUD), the intramuscular or subcutaneous injection DepoProvera™ (injection), and the subdermal implant Nexplanon™ (implant).

1.4 Allhormonal contraceptives available in the US contain progestin only or a combination of estrogen and progestin. Hormonal contraceptive forms that contain a progestin with an estrogen include COCs, patch, and ring. The safety profiles for hormonal contraceptives containing progestin and estrogen together are generally favorable, and some studies suggest that the only essential information prior to provision is medical history and blood pressure (Wahlin et al, 2014; Xu et al, 2014).POPs, injection, implant, and LNG-IUD are the hormonal contraceptives available in the US that only contain a progestin. These contraceptives have a more favorable safety profile due to the absence of estrogen (White et al, 2012; Bowers, 2012; Grossman, 2013; Richters, 2013).This highly favorable safety profile of progestins is probably one of the main reasons why progestin-only emergency contraceptives were granted BTC and OTC status.

1.5 Increasing access to hormonal contraception can be a helpful way to increase the use of hormonal contraception and decrease unintended pregnancies. Hormonal contraceptives that could be made more accessible in pharmacies include COCs, POPs, patch, ring, and injection. Increasing access to these contraceptives could be achieved in several ways. One model could be to allow pharmacists to have prescriptive authority for some hormonal contraceptives, which could be achieved with collaborative practice agreements with licensed prescribers. A second model could be to grant some hormonal contraceptives BTC status, allowing non-prescriptive access with additional restrictions such as age and gender. A third model could be to grant some hormonal contraceptives status as OTC medications without any restrictions.

1.6 There are several reasons why a pharmacist may or may not support any or some of these models of expanding access to hormonal contraceptives. Three of these major reasons may include the type of hormonal contraception, confidence to properly screen for contraindications, and/or confidence in patients to properly self-screen for contraindications. Our study therefore surveyed pharmacists about these three major reasons that may affect their attitudes towards expanding access to hormonal contraception in pharmacies. This study is also the first to report pharmacists' attitudes towards three different models for increasing access to hormonal contraception: the pharmacist-prescribed model, the BTC model, and the OTC model.

2.0 Materials and Methods

2.1 The survey questionnaire included6 multiple choice questions and 25 Likert scale questions. The survey included three areas: 1) demographic information; 2) attitudes about increasing access to different hormonal contraceptives; and 3) confidence about screening for contraindications to different hormonal contraceptives. The draft survey was pilot-tested by a small convenience sample of pharmacists not involved with the initial draft of the survey. Based on feedback from the pilot testing group the survey was improved for organization, readability, and clarity. The survey and study protocol were approved by the Shenandoah University Institutional Review Board.

2.2 Thirty-two chain and independent retail pharmacies in Winchester, Virginia were approached for participation in March, 2011. A total of 52 surveys, with accompanying materials, we redistributed to all the pharmacies based on the number of pharmacists employed at each location during that week. The materials distributed for each pharmacist at each location included a survey, a letter with survey instructions and contact information, and a small envelope. The letter instructed each pharmacist to complete the anonymous survey within the next several days, place the survey in the small envelope to ensure confidentiality, and then place the small envelope into a single, larger envelope that was provided to each location. The exact wording of the Likert scale questions provided to the pharmacists are shown in the tables, no additional information was provided. No incentives were provided for participation. One week after the distribution of the materials, the single large envelope containing the small envelopes with the surveys was collected from each location.

2.3 All the data from the completed surveys were entered into and analyzed with Excel (2010 version, Microsoft Corporation, Redmond, Washington). Descriptive statistics were performed for all data. Data are presented as frequency and percent of responses. One-way analysis of variance (ANOVA) was used to measure significance among the Likert item data for each of the different access type questions and screening questions. Differences in the Likert item responses between each contraceptive were calculated using Tukey-Kramer minimum significance. Statistical significance was set at $p<0.05$.

3.0 Results

3.1 Fifty-two surveys were distributed to pharmacists and 33 completed surveys were collected for a response rate of 63%. Table 1 shows the demographics of the responding pharmacists. The majority of the pharmacists were female (61%), possessed a doctor of pharmacy degree (55%), worked at a chain retail pharmacy (91%), and were Caucasian (88%).

Table 1: Demographics of the Pharmacists

	Responses *n* (%), *N*=33[a]
Gender	
Male	10 (30)
Female	20 (61)
Highest Degree	
Doctor of pharmacy	18 (55)
Bachelor of science	13 (39)
Pharmacy type	
Chain	30 (91)
Independent	2 (6)
Years of practice	
Less than 1	3 (9)
1-5	10 (30)
6-14	8 (24)
15-25	5 (15)
More than 25	6 (18)
Age (years)	
Under 25	2 (6)
25-34	14 (42)
35-44	7 (21)
45-60	4 (12)
Over 60	3 (9)
Ethnicity	
Caucasian	29 (88)
African-American	0 (0)
Asian	0 (0)
Hispanic	0 (0)
other	0 (0)

[a]Responses may total less than 33 for each question because some respondents skipped some questions.

3.2 Table 2 demonstrates the pharmacists' attitudes about increased access to hormonal contraception at pharmacies. In regard to allowing pharmacists to prescribe each of the forms of hormonal contraceptives in a retail pharmacy setting, the pharmacists demonstrated more disapproval (a range of 51% - 57% selected disagree or strongly disagree for each of the contraceptives) than approval (a range of 27% - 30% selected agree or strongly agree for each of the contraceptives). The pharmacists demonstrated even stronger disapproval (a range of 68%-75% selected disagree or strongly disagree for each of the contraceptives) for allowing pharmacists to dispense any of the forms of hormonal contraceptives as a non-prescription, BTC product. The pharmacists demonstrated the strongest disapproval (a range of 94% - 97% selected disagree or strongly disagree for each of the contraceptives) for allowing any of the forms of hormonal contraceptives to be available as a traditional OTC product. Within each of the three access questions, there were not any statistically significant differences between the responses for the different forms of contraception.

Table 2: Pharmacists' Attitudes about Expanding Access to Hormonal Contraception

	Response, *n* (%), *N*=33[a]				
Question: Pharmacists (with or without a collaborative agreement with a physician) should be allowed to prescribe the following hormonal contraceptives to female patients in a retail setting:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
estrogen and progestin pills	6 (18)	12 (36)	5 (15)	5 (15)	4 (12)
progestin-only pills	6 (18)	11 (33)	5 (15)	6 (18)	4 (12)
OrthoEvra® (patch)	6 (18)	13 (39)	3 (9)	6 (18)	4 (12)
NuvaRing® (ring)	6 (18)	13 (39)	4 (12)	7 (21)	2 (6)
DepoProvera® (injection)	6 (18)	13 (39)	4 (12)	6 (18)	3 (9)
Question: Pharmacists should be allowed to dispense the following hormonal contraceptives as a behind-the-counter item (available without a prescription to females only, ages 17 and older, with the offer of pharmacist counseling):	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
estrogen and progestin pills	7 (21)	17 (52)	1 (3)	3 (9)	3 (9)
progestin-only pills	8 (24)	14 (42)	1 (3)	5 (15)	4 (12)
OrthoEvra® (patch)	8 (24)	16 (48)	3 (9)	2 (6)	3 (9)
NuvaRing® (ring)	9 (27)	16 (48)	2 (6)	3 (9)	2 (6)
DepoProvera® (injection)	11 (33)	14 (42)	2 (6)	3 (9)	2 (6)
Question: The following hormonal contraceptives should be available as an over-the-counter item (no restrictions on age, gender, or quantity):	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
estrogen and progestin pills	18 (55)	13 (39)	0 (0)	1 (3)	0 (0)
progestin-only pills	18 (55)	13 (39)	0 (0)	1 (3)	0 (0)
OrthoEvra® (patch)	18 (55)	13 (39)	0 (0)	1 (3)	0 (0)
NuvaRing® (ring)	19 (58)	13 (39)	0 (0)	0 (0)	0 (0)
DepoProvera® (injection)	20 (61)	12 (36)	0 (0)	0 (0)	0 (0)

[a] Responses may not total 33 for each question because some respondents skipped some questions

3.3 Table 3 demonstrates pharmacists' confidence about their ability to screen for contraindications to pharmacist-prescribed hormonal contraception. The majority of pharmacists demonstrated confidence (a range of 60% - 61% selected agree or strongly agree) about screening for contraindications to all the forms of hormonal contraceptives, while a minority demonstrated a lack of confidence (18% selected disagree or strongly disagree) about screening for contraindications to all the forms of hormonal contraceptives. Table 3 also demonstrates pharmacists' confidence about the ability of patients to self-screen for contraindication to OTC hormonal contraceptives. The strong majority of pharmacists demonstrated a lack of confidence (a range of 82% - 88% selected disagree or strongly disagree) about the ability of patients to self-screen for contraindications to all the forms of hormonal contraceptives as OTC products. Within each of the two screening questions, there were not any statistically significant differences between the responses for the different forms of contraception.

Table 3: Pharmacists' Confidence about Screening for Contraindications to Hormonal Contraception

	Response, *n* (%), *N*=33[a]				
Question: With regards to pharmacist-prescribed hormonal contraceptives, I can appropriately screen for contraindications to the following:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
estrogen and progestin pills	4 (12)	2 (6)	6 (18)	16 (48)	4 (12)
progestin-only pills	4 (12)	2 (6)	6 (18)	17 (52)	3 (9)
OrthoEvra® (patch)	4 (12)	2 (6)	6 (18)	17 (52)	3 (9)
NuvaRing® (ring)	4 (12)	2 (6)	6 (18)	17 (52)	3 (9)
DepoProvera® (injection)	4 (12)	2 (6)	6 (18)	17 (52)	3 (9)
Question: With regards to hormonal contraceptives being available as an over-the-counter item, patients can appropriately self-screen for contraindications:	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
estrogen and progestin pills	22 (67)	5 (15)	3 (9)	2 (6)	0 (0)
progestin-only pills	22 (67)	6 (18)	2 (6)	2 (6)	0 (0)
OrthoEvra® (patch)	22 (67)	6 (18)	2 (6)	2 (6)	0 (0)
NuvaRing® (ring)	22 (67)	7 (21)	1 (3)	2 (6)	0 (0)
DepoProvera® (injection)	23 (70)	6 (18)	1 (3)	2 (6)	0 (0)

[a] Responses may not total 33 for each question because some respondents skipped some questions

4.0 Discussion

4.1 The majority of the responding pharmacists in our study did not support expanding access to any of the different types of hormonal contraception. Another study found that only 15% of pharmacists were not interested in expanding access to hormonal contraception (Landau et al, 2009). This prior study distributed electronic surveys to 14142 pharmacists throughout the US, resulting in 2745 respondents (19% response rate). The national surveys were administered in November 2004 to December 2005, and published in 2009.

4.2 The difference in pharmacist attitudes between the two studies could be due to any of the differences between the surveys. Our study reflects attitudes of one specific city and the other survey reflects national attitudes, although the national study reported no difference between regional attitudes. The national survey had a much lower response rate than ours (19% vs 63%, respectively) and also provided incentives to participate, which we did not. Our data is six years more recent than the national data and could reflect a shift in attitudes.

4.3 Although the majority of the pharmacists in our study did not support pharmacist-prescribed hormonal contraception, the majority of the pharmacists did demonstrate confidence in their ability to appropriately screen for contraindications. The national survey of pharmacists also found that the majority of responding pharmacists were comfortable with performing activities that ensured a woman was an appropriate candidate for hormonal contraception (Landau et al, 2009). In support of this, almost all of the physicians and advanced practice clinicians in a study viewed pharmacists as competent for evaluating patients for the use of hormonal contraception (Rafie et al, 2012).

4.4 The national survey also demonstrated that the top reasons for pharmacists not being interested in offering pharmacy access to hormonal contraceptives were time constraints, resistance from physicians, and belief that a pelvic exam and pap smear were necessary for prescribing safely (Landau et al, 2009). Interestingly, physicians and advanced practice clinicians reported refusal of care by pharmacists as their most common concern about pharmacy access to hormonal contraceptive, but did express a similar concern as the pharmacists about resultant time constraints and supported appropriate reimbursement for pharmacists (Rafie et al, 2012).

The practice recommendations for hormonal contraceptive use published by the Centers for Disease Control state that pelvic exams and pap smears "do not contribute substantially to safe and effective use of the contraceptive method" (Centers for Disease Control, 2013). Unlike our survey, the national survey included background information in the introduction of the survey about the non-requirement of a pelvic examination and Pap smear for prescribing hormonal contraception. This may be one of the most important and optimistic reasons for the national survey reporting a larger percent of pharmacists supporting expanded access to hormonal contraceptives than our study.

4.5 In contrast to most of the pharmacists in our study who did not support pharmacist-prescribed hormonal contraception, a survey of pharmacy students in California demonstrated that 96% are interested in providing direct hormonal contraception services if they were available under a statewide collaborative protocol with a prescriber (Rafie et al, 2011). Additionally, the Direct Access study in Washington state has demonstrated successful feasibility of this concept with community pharmacists (Gardner et al, 2008).

4.6 In addition to not supporting pharmacist-prescribed hormonal contraception, a larger majority of pharmacists in our study did not demonstrate support for allowing hormonal contraceptives to have limited non-prescription access as BTC products. The national survey of pharmacists' attitudes on expanded access to hormonal contraception did not report specifically about BTC access (Landau et al, 2009). An informal, online poll at www.uspharmacist.com in 2011 asked visitors if oral contraceptives should be available without a prescription as a "behind the counter" item (Cohen, 2011). Forty-seven percent of the respondents did not approve of oral contraceptives being BTC because of too many safety risks. Similar to products in the US that have or have had BTC status, BTC access to hormonal contraceptives could include restrictions based on age, gender, purchase quantity, proof of identification, and/or the offer of counseling by a pharmacist (Pray et al, 2011).

4.7 Oral contraceptives have been demonstrated to meet all the main criteria that the FDA considers with regard for switching a prescription drug to an OTC drug (Wahlin et al, 2014; Grossman et al, 2013).

Granting OTC status to hormonal contraceptives would increase their availability which may also increase their continuation rates. In fact, women who received their oral contraceptives as OTC products demonstrated lower discontinuation rates than women who received prescribed oral contraceptives from a clinic (Potter et al, 2011).

4.8 Of all the pharmacy-access models, the pharmacists in our study demonstrated the least support for hormonal contraceptives being available as traditional OTC products. The national survey of pharmacists' attitudes on expanded access to hormonal contraception did not report specifically about OTC access or confidence in the ability patients to self-screen (Landau et al, 2009). Almost every pharmacist in our study disagreed with the ability of patients to appropriately self-screen for contraindications. This concern of patient self-screening may be one of the main factors that pharmacists do not support hormonal contraceptives as a non-prescription drug. A survey of physicians demonstrated that 92% of those who did not support switching COCs to OTC expressed safety as the primary concern (Howard et al, 2013). Two studies with 1271 women and 392 women demonstrated that 93% and 95%, respectively, were able to appropriately self-screen for contraindications to COCs (Grossman et al, 2008; Shotorbani et al, 2006).

4.9 Analysis of the data in our study showed that there were no statistically significant differences in the attitudes of the pharmacists towards any of the specific forms of hormonal contraception. The national survey did not report about pharmacists' attitudes toward expanding access to different forms of hormonal contraception (Landau et al, 2009). Pharmacists in our study did not demonstrate preference for increasing access to progestin-only contraceptives compared to estrogen-containing contraceptives. For example, ninety-seven percent of the pharmacists were equally against COCs or POPs being OTC. This was surprising due to POPs having fewer contraindications than COCs (White et al, 2012). The increased safety profile of POPs has resulted in the proposal of POPs as the best choice for the first OTC hormonal contraceptive (White et al, 2012; Bowers, 2012; Grossman, 2013).

4.10 The results of our study may not reflect the attitudes and confidence of other pharmacists about hormonal contraception due to the small sample size, narrow geographic region, predominance of chain retail pharmacists, and the racial homogeneity of the participants.

Future studies on this topic should aim for a larger and broader survey population, while maintaining a high response rate. Some future studies may also incorporate qualitative research methods to better elucidate why pharmacists may not support the different types of pharmacy-initiated access to hormonal contraceptives. Researchers, educators, and policy-makers should continue to do their best to keep pharmacists involved, informed, and engaged in the goal of reducing unintended pregnancies.

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