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Online availability of hormonal contraceptives without a health care examination: Effect of knowledge and health care screening

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Abstract

Background—The study was conducted to investigate whether the knowledge of women using an online resource to obtain hormonal contraceptives (HC) without a health care examination is similar to women who obtain HC in the clinic.

Study design—Women who accessed HC prescriptions online or through a clinic visit were offered an anonymous, self-administered survey regarding the contraindications to and possible complications of HC. Tests of equivalence were used to compare the mean scores between the two populations.

Results—Online users (n = 243) were older, more affluent, more educated, and more likely to be insured than clinic patients (n = 161). The two populations demonstrated equivalent HC knowledge [contraindications (mean score, 95% confidence interval): clinic 81.1% (77.2%, 85.0%), online 85.0% (82.0%, 88.0%); complications: clinic 77.6% (72.7%, 82.6%), online 82.1% (78.8%, 85.5%)]. The online population remained equivalent or superior to the clinic population in an age-restricted analysis.

Conclusion—Women who self-select to obtain HC prescriptions online demonstrate at least equivalent knowledge of potential HC risks as women seen in a clinic encounter without a pelvic exam.

Keywords

Hormonal Contraception; Online Health Care; Family Planning

1. Introduction

Current evidence does not support the requirement for a breast and pelvic exam before prescribing contraception [1–3]. As early as 1994, the U.S. Food and Drug Administration (FDA) stated that a physical examination may be deferred until after initiation of oral contraceptives [4]. In 1999, Planned Parenthood Federation of America (PPFA) issued a

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statement allowing deferral of pelvic examinations for up to 13 months after initiation of hormonal contraception (HC) [5]. The World Health Organization, in 2000, issued a comprehensive review of contraindications to the use of HC [6,7], all of which can be detected using a medical history and blood pressure check, rather than a breast or pelvic exam.

Strategies that reduce barriers to obtaining a prescription for HC may improve access to these methods and reduce the number of unplanned pregnancies and abortions. Currently, 113 million American adults have searched for health information online [8]. However, computer-based online health screening is an under investigated strategy in family planning practice.

Given the widespread public use and acceptance of the Internet as a resource for health information, the incorporation of the Internet into clinical practice represents a logical extension. In 2004, as an adjunct to allowing women to obtain HC without a pelvic exam during a clinic visit, Planned Parenthood of the Columbia/Willamette, Portland, Oregon (PPCW), became the first family planning providers in the nation to offer an online program to obtain contraception. The “hormones with optional pelvic exam” (HOPE) program allows qualified women to obtain prescriptions for contraception through the Internet without a clinic-based health care encounter. To explore the hypothesis that obtaining HC via the Internet provides equivalent screening as a face-to-face clinic appointment, we investigated whether the knowledge of complications and contraindications to HC use among women using the HOPE option was similar to that of women who obtained a prescription through an encounter in the clinic.

2. Materials and methods

2.1. Design

The Oregon Health & Science University institutional review board and the Planned Parenthood of the Columbia/Willamette (PPCW) board of directors approved the study protocol. Completion of the survey implied consent. The clinic population consisted of women presenting to PPCW’s Salem or Beaverton clinics between November 2005 to May 2006 as first-time users of the “pills without a pelvic” (PWOP) program. Although a pelvic examination is not required for HC in the PWOP program, health history is reviewed in person with a clinic nurse. PWOP clients that agreed to participate received a paper survey. The online population consisted of first-time users of the HOPE online website between October 2005 to January 2006.

First-time users of either the HOPE online or PWOP clinic program (non-refill appointments) were chosen to reduce the confounding introduced by receiving education about HC multiple times from similar visit types. Both surveys were administered at the end of the encounter to ensure that both groups of women were exposed to the full educational content of their respective care venues regarding the risks, contraindications, and benefits of HC. Clinic subjects were offered a paper survey only after the completion of their appointment, while online subjects completed the selection and purchase of a HC method prior to receiving study information and a link to the web-based survey. Women in both groups were offered two movie tickets for their participation. The surveys were identical aside from their method of dispersal.

The questionnaire was designed to identify knowledge of the risk factors of HC and to collect demographic data about the women using the services. Knowledge questions were developed to assess the subjects’ understanding of generally agreed upon criteria for contraindications to use and potential dangerous complications from HCs, using PPFA, FDA, and WHO consensus information [4–7].

Information regarding the contraindications, risks, and benefits of HC were given to women by trained health care professionals in the PWOP clinics and via links to specific types of contraception on the HOPE online site. Women were counseled in the clinics about who should not take HC and specific conditions are listed on the website, that are contraindications to HC, such as age 35 or older and smoke cigarettes or have a history of heart attack or stroke. The true contraindications in the first knowledge question in the survey were all taken from PPCW's standardized materials about HC given both in the clinic and online. The risks of HC and how to recognize the warning signs are also detailed on the website or discussed with a trained health care professional in the clinic and include for example; sudden shortness of breath or unusual swelling or pain in the arm or leg. The true possible complications of HC used in the survey were also all from PPCW's standardized materials. The various benefits to HC are also listed, such as protection from ectopic pregnancy, uterine lining and ovarian cancers, and decreased iron deficiency anemia in women with heavy menstrual bleeding.

2.2. Measures

Question 1 asked the participant to identify the correct contraindications to HC from a list of 11 possible choices (Table 1). **Question 2** asked the subject to correctly identify potentially dangerous side effects of HC from a list of 10 possible side effects (Table 2). Of these, seven represented true contraindications while four were false contraindications. False contraindications and potentially dangerous side effects were included to discriminate between the participants' knowledge of the risks of HCs versus their ability to guess correctly. In addition, basic demographic information including prior and current contraception type and use and type of contraception use was collected. Questions were either true or false, multiple choice, or 5-point Likert scale.

2.3. Analysis

A score was calculated for **Question 1** and **2** by determining the proportion correct out of *all* (both true and false) contraindications or complications (total score) and proportion correct out of the *true* contraindications or complications (final score). The number of subjects who answered True to every individual question or False to every individual question was monitored, as it possibly reflected subjects not thoughtfully filling out the survey, but rather just filling out the same column for all responses. A two-sample t-test of equivalence was used to assess whether the mean percentage correct was equivalent between the two populations [9]. The two populations' knowledge was considered equivalent when the upper and lower bounds of the 95% confidence interval of the mean difference did not exceed one and a half questions difference for the total score (Q1 = 13.6%; Q2 = 15%) and one question difference for the final score (Q1 = 14.3%; Q2 = 20%). This was deemed a clinically significant difference because the final scores were made up of only the major risk factors of HC; therefore, having a one question difference among the populations was considered harmful. All analyses were completed using SPSS (version 13.0; SPSS Inc, Chicago, IL). *A priori*, we had 80% power with an alpha of 0.05 for the test of equivalence with n = 136 per group assuming a 50% proportion correct.

Chi-square tests were calculated to compare categorical demographic variables clinic and the online populations (age, race/ethnicity, education, income, language spoken at home); health insurance status; and main form of contraception used in past year.

Since the baseline characteristics of the two groups differed, an age-restricted subgroup of data on ages 20–29 was analyzed for equivalency, as age was the major marker of the other differences (e.g., income, education, and health insurance status). ANCOVA was used to obtain the standard errors to generate the confidence intervals for the test of equivalence between the

mean scores of the two populations after adjusting for the possible predictive or confounding variables.

3. Results

There were 267 users of the online site (HOPE) during the study period, and 243 completed surveys, for a response rate of 91.0%. A total of 171 clinic-based surveys (PWOP) were returned, 161 of which were complete. We could not obtain a complete record of first-start clinic-based patients; therefore, we could not calculate a response rate for our clinic-based questionnaire.

The general comparative population of all PPCW clients (n=22,052) seen during the study interval was significantly less affluent (62% with income below \$10,000, $p < 0.0001$), younger (26% < 20 , $p = 0.0371$), less educated (26% had not completed high school, $p < 0.0001$), but better insured (81% with health care coverage, $p < 0.0001$) than the combined study population of HOPE and PWOP clients. Comparing the two study populations, the online cohort was significantly more likely to have used HC within the past year ($p < 0.0001$), and to be insured ($p < 0.0001$), older ($p < 0.0001$), non-Latina ($p < 0.0001$), more highly educated ($p < 0.0001$), and more affluent ($p < 0.0001$) than the clinic subjects (Table 3).

The two study populations had equivalent total scores on the contraindications to HC (**Question 1**: clinic-based = 71.15, online = 73.18) and on the warning signs of serious events related to HC (**Question 2**: clinic-based = 70.31, online = 74.69) (Table 4). Since the proportion of subjects answering incorrectly to the false sub-questions was the same for both groups, a final score was computed by removing the false sub-questions. The scores between the groups were statistically equivalent to one another for both comparisons. Only 7 surveys, 4 in the clinic and 3 in the online group, had all true responses, but including or removing these scores did not change the overall outcome of the analysis. Although the overall results did not change in the age-restricted analysis, the online group showed superior knowledge on **Question 2** (**Question 1**: clinic-based = 82.65, online = 85.71; **Question 2**: clinic-based = 75.71, online = 83.86) (Table 5).

4. Discussion

Services that increase access to HC may have a positive influence on utilization of family planning services (initiation and continuation of contraception) and reduce unintended pregnancy. Offering HC prescriptions online to eligible women represents a novel approach to improve access, but concerns about inappropriate use limit its acceptability. Our results demonstrate no substantial reason to be concerned, in that women who access HC online or in an office visit have equivalent knowledge of HC contraindications and warning signs.

In our study, women who used the online resource to obtain HC were more affluent, educated, older, and better insured than the clinic-based group. The self-selection that occurred with the online population is not unexpected since there are barriers to using computers for many (particularly low-income) women, and a credit card is necessary to pay for the online prescription.

We found that our online population had equivalent knowledge regarding HC contraindications and complications as women who visited a provider in the office. Despite the differences in baseline characteristics, these results were robust and did not differ after matching on age and controlling for other confounders (insurance, contraception use, age, Latina ethnicity, race, language, education, and income). Moreover, both cohorts of women in our study demonstrated high levels of knowledge of HC risks. This is comparable or higher to other types of patient health care knowledge reported in the medical literature [10,11].

This study provides important information characterizing a population of women who self-selected to use an online resource to obtain HC. As PPCW is the first family planning organization to provide contraceptive prescriptions online, this is critical information, especially as plans move forward to make this a national program within PPFA. These data were representative of the population of women who self-select to obtain contraception online and can be generalized to online women in general. Moreover, since the PWOP and HOPE population was not representative of all PPCW patients obtaining HC in a usual health care interaction involving a physical examination, our conclusions cannot be generalized to the overall population of family planning clients. Furthermore, although we only studied new starts in the PWOP and HOPE programs, we did not directly compare either of these groups specifically to new starts seen for a traditional clinic encounter. However, since the primary purpose of these visits is to provide access to an effective contraceptive method, our results support the conclusion that women seeking HC online have enough information to safely use the method.

This study provides important information characterizing a population of women who self-selected to use an online resource to obtain HC. Although population differences exist, our data suggest that women seeking HC outside of a traditional health care encounter have equivalent knowledge of contraindications and treatment-emergent problems as a clinic exam-free group. HC are safe, effective, and well-studied drugs that may achieve over-the-counter status in the near future [1,12]. Computer-assisted patient education and online prescriptions may be a valuable bridge until that occurs.

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Table 1

Question 1 from a survey testing knowledge of the risk factors of hormonal contraception in women seeking contraception from PPCW without a pelvic exam

“I would not use the Pill, the Ring, or the Patch if I had a history of the following (Mark TRUE or FALSE):”

- Iron deficiency anemia
 - Blood clots in veins or arteries
 - Liver disease
 - Heart attack
 - Stroke
 - Thyroid disease
 - Migraine with aura (visual symptoms before or during the headache, numbness or tingling, slurred speech, or dizziness)
 - Irregular periods without heavy bleeding
 - Age over 35 years and smoke cigarettes
 - Recent abortion
 - High blood pressure
-

Italics denote correct responses.

Table 2

Question 2 from a survey testing knowledge of the risk factors of hormonal contraception in women seeking contraception from PPCW without a pelvic exam

“Of the following possible symptoms, which are warning signs of health problems that might be caused by taking the Pill, the Ring, or the Patch that I should report to a clinician (Mark TRUE or FALSE):”

- Nose bleed
- Severe chest pain or coughing blood
- Severe shortness of breath
- Red, swollen, or painful leg or arm
- Sudden severe headaches
- Nausea
- Dry mouth
- Severe pain in stomach or abdomen
- Joint pain
- Bloating

Italics denote correct responses.

Demographic characteristics among the study population of women obtaining prescriptions for hormonal contraception without a pelvic exam at PPCW

Table 3

	Clinic (n = 161)		Online (n = 243)		X ²	p-value
	n	%	n	%		
<u>Insurance</u>						
No	109	68.4	116	48.3	15.549*	< 0.0001
<u>Contraception</u>						
Not hormonal	86	52.5	51	21.0	42.818*	< 0.0001
<u>Age (yrs)</u>						
≤16	21	13.0	2	0.8	101.734*	< 0.0001
17 – 19	47	29.2	15	6.2		
20 – 24	66	41.0	82	33.7		
25 – 29	18	11.2	89	36.6		
30 – 34	6	3.7	33	13.6		
≥35	3	1.9	22	9.1		
<u>Latina ethnicity</u>						
No	143	88.8	232	95.5	6.373*	0.012
<u>Race</u>						
Not White	31	19.3	35	14.4	1.668	0.197
<u>Language</u>						
Not English	10	7.5	7	3.7	2.763	0.096
<u>Education</u>						
< High school	35	21.7	3	1.2	109.491*	< 0.0001
Completed HS or GED	54	33.5	23	9.5		
Some college or 2 yr college	48	29.8	95	39.1		
College graduate	22	13.7	98	40.3		
Graduate school	2	1.2	24	9.9		
<u>Income</u>						
Don't know	44	27.3	11	4.5	77.672*	< 0.0001
< \$5000	32	19.9	25	10.3		
\$5,000 – 9,999	24	14.9	31	12.8		

	Clinic (n = 161)		Online (n = 243)		X ²	p-value
	n	%	n	%		
\$10,000 – 19,999	32	19.9	42	17.3		
\$20,000 – 39,000	21	13.0	84	34.6		
≥\$40,000	8	5.0	50	20.6		

* Statistically significant at p < 0.05 level.

Table 4

Mean scores of knowledge of the risk factors of hormonal contraception (HC) among women obtaining HC without a pelvic exam at PPCW (n = 404)

	Mean score (%)		Mean difference (%)	95% Confidence interval (%)
	Clinic (161)	Online (243)		
Q1 total score *	71.15	73.18	-2.03	-5.05, 0.99
Q1 actual score †	81.10	85.01	-3.91	-8.75, 0.94
Q2 total score	70.31	74.69	-4.38	-8.21, -0.56
Q2 actual score	77.64	82.14	-4.50	-10.24, 1.24

* Total score = number of correct responses out of the total number of answer choices.

† Actual score = number of correct responses out of the total number of actual contraindications or complications of HC, without the false sub-questions.

Table 5

Knowledge of risk factors of hormonal contraceptives among a sub-group of women, ages 20 – 29 years, at PPCW

	Mean score (%)		Mean difference (%)	95% CI (%)
	Clinic (n)	Online (n)		
Question 1	82.65 (84)	85.71 (171)	-3.1	-9.0, 2.9
Question 2	75.71 (84)	83.86 (171)	-8.2	-15.2 [‡] , -1.1

[‡]Clinic population does not have equivalent knowledge using <15% difference.