

ONLINE AVAILABILITY OF HORMONAL CONTRACEPTIVES WITHOUT A
HEALTH CARE EXAMINATION: EFFECT OF KNOWLEDGE AND HEALTH
CARE SCREENING.

by

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CERTIFICATE OF APPROVAL


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List of Abbreviations

ANCOVA Analysis of Covariance

DHS..... Department of Human Services

EE..... Ethinyl Estradiol

FDA..... Food and Drug Administration

HC Hormonal Contraception

HOPE Hormones with Optional Pelvic Exam

OC Oral Contraceptives

OTC..... Over-The-Counter

PPCW.....Planned Parenthood of the Columbia/Willamette

PPFA Planned Parenthood Federation of America

PWOP Pills With Optional Pelvic

WHO World Health Organization

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“In art nothing worth doing can be done without genius, in science even a very moderate capacity can contribute something to a supreme achievement.”

- Bertrand Russell

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Abstract

Objective: To investigate whether the knowledge, safety, and health screening behavior of women using an online resource to obtain hormonal contraceptives (HC) without a health care examination was similar to women who obtained HC in the clinic.

Methods: Women who accessed HC prescriptions online and those that obtained prescriptions during an office visit were surveyed regarding knowledge and risks of HC. Knowledge of the contraindications to HC use and for awareness of possible dangerous complications of HC was assessed using two multiple choice questions. A score with actual and false contraindications and a score with actual and false dangerous complications associated with HC were calculated from the survey. The two outcomes were the proportion correct out of *all* contraindications or complications (total score) and proportion correct out of the *true* contraindications or complications (final score). Tests of equivalence were used to compare the mean scores between the two populations. The criteria for the equivalence of the online population to the clinic population occurred when the bounds of the 95% confidence interval of the mean difference did not exceed one and a half questions difference for the total score and one question difference for the final score

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 were equivalent in HC knowledge [contraindications mean score: clinic 81.1% (77.2%, 85.0%), online 85.0% (82.0%, 88.0%); complication mean score: clinic 77.6% (72.7%, 82.6%), online 82.1% (78.8%, 85.5%)]. After restricting the two populations in an analysis based on age, the online population was not worse than the clinic population.

Conclusion: Women who self-selected the use of an online resource to obtain HC prescriptions differ demographically from their clinic counterparts. Women who obtain birth control online demonstrate equivalent or better levels of knowledge of potential HC risks as women seen by a provider in clinic. Both approaches at obtaining HC prescriptions appear safe. These results challenge the traditional belief that use of hormonal contraception requires a face-to-face contact with a health care provider.

Chapter 1 – Introduction

Oral contraceptives (OCs) are the most widely used form of birth control in the United States (1). Over 106 million women use OCs worldwide (2). OCs became available in the 1960s and contained roughly the equivalent of 120mcg of ethinyl estradiol (EE) and 10,000 mcg of progestin (3). Modern OCs only contain 20 to 35 mcg of EE and 100 to 1,000 mcg of progestin. An estrogen-free product (the progestin only pill) also exists on the market.

Researchers and industry have changed formulations of OCs to make them safer, more acceptable, and easier to use. The most significant alteration since their introduction in the 1960s has been low-dose hormone formulations that are associated with a reduced risk of adverse cardiovascular events including stroke, blood clots, and myocardial infarction (4). The risks of OCs are still lower than those associated with pregnancy (5). The safety and efficacy of hormonal birth control has been well documented (6,7). In fact, hormonal contraception represents one of the most extensively studied classes of medications, with a low incidence of serious complications from chronic use (8-10).

Despite this safety record, over-the-counter (OTC) status for oral contraceptives remains controversial. Opponents argue that OTC status for hormonal birth control would reduce health care screening for women and that OTC status would increase the population risk by allowing women with contraindications to hormonal contraception (HC) access to the products. Proponents counter that a woman's health screening should occur during a well-woman visit, and that HCs are safe drugs that can effectively prevent unintended pregnancies and thereby reduce abortions, both of which are riskier than HC

use. As over half of the pregnancies in the U.S. are unplanned, this is an important debate for women (11).

Traditionally, breast and pelvic exams have been required to obtain hormonal birth control. When oral contraceptives were first introduced in the 1960s, less was known about the health risks and a complete medical examination was the standard of care. Now that more is known of the risks and long-term consequences, it is clear that a focused exam is more appropriate. The requirement of a pelvic examination can be a barrier to many women trying to obtain contraception, especially young women. The financial barriers to health care exams may also present a burden to the 28 percent of the 43 million uninsured in the U.S. are women of childbearing age) (12,13). Although averting cervical cancer is an important health screening intervention, birth control is used for the prevention of unplanned pregnancy and contraindications to use are not screened with traditional breast and pelvic exams. The best screening for the risks of contraception is via a thorough medical history and a blood pressure measurement. Counseling and screening for sexually transmitted infections can still be performed during the appointment without a physical exam, now that better collection methods have been developed (14).

As providers have become more knowledgeable about the safety of hormonal contraception, the standard of care has been changed to no longer require a breast and pelvic exam before prescribing contraception (14). These exams are now viewed as part of the routine health care screening undertaken during a well-woman visit (15,16). Annual Pap smears are no longer standard outside of the U.S. 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 (17). In 1999, Planned Parenthood Federation of America (PPFA) issued a statement allowing deferral of pelvic examinations for up to 13 months after initiation of hormonal contraception (18). The World Health Organization (WHO), in 2000, issued a comprehensive review of the contraindications to the use of HC (19,20), all of which are best detected using a medical history and blood pressure check, rather than a breast or pelvic exam. Following this report, Planned Parenthood of the Columbia/Willamette (PPCW) initiated the “Pills With Optional Pelvic” program (PWOP), allowing women in their clinics to obtain contraception without a pelvic exam.

Strategies that reduce barriers to obtaining a prescription for hormonal contraception may improve access to these methods and reduce the number of unplanned pregnancies and abortions. Computer-based online health screening is one such strategy that has received little attention in practice. Many Americans are obtaining health information online. Eighty percent of American internet users, representing approximately 113 million adults, have searched for health information online (21). Over half of these people report their search affected a decision about how to treat an illness, or the information changed their overall approach to maintaining their health. Certain groups of internet users are most likely to search for health information: women, people younger than 65 yrs, college graduates, those with more online experience, and those with high-speed internet access (22).

Barriers to internet access have been investigated among women. A survey of women in King County, WA that examined internet access demonstrated that level of mental health, level of general health perceptions, older age, and higher income predicted

women's health-related internet use (23). Lack of access was related to perceived lack of usefulness of the internet as an information source, unfamiliarity with the technology, and financial barriers. Therefore any internet health service would have to take these factors into account in order to reach a large proportion of women.

Adolescents are also very likely to use the internet. A survey of internet users aged 15 – 24 years found that 90 percent had been online and that 75 percent sought health information (24). For confidential issues like birth control, it provides a way to investigate these concerns without adult intrusion. The internet was found to have an important place among adolescents' health information sources (25). But like older women, the usefulness of the internet depends on access.

Given the wide use of the internet by the public, especially for seeking health information, a next step could be to incorporate the internet into clinical practice. Psychiatrists have already begun using email as a communication tool with their patients (26). Online communications have been predicted by some to replace a substantial amount of face-to-face encounters with a clinician (27). But there has been little research into how effective these online health services are at present. A review of the literature of computerized educational interventions demonstrated that they can be a beneficial complement to, rather than a substitute for, in-person time with physicians (28,29).

In 2004, PPCW became the first family planning providers in the nation to offer an online program, "Hormones with Optional Pelvic Exam" (HOPE) that allows qualified women to obtain prescriptions for contraception through the internet. To explore the hypothesis that the internet can be an adequate replacement for a face-to-face appointment to obtain HC, we investigated whether the knowledge, safety, and health

screening behavior of women using an online resource to obtain HC without a health care examination was similar to women who obtained a prescription through an in-clinic encounter.

Chapter 2 – Materials and Methods

Participants

The Oregon Health & Science University institutional review board and the PPCW board of directors approved the study protocol. In November, 2005 and May, 2006, all women who came to PPCW's Salem or Beaverton clinics as first-time users (rather than women seeking refills) of the "Pills With Optional Pelvic" (PWOP) program were invited to participate in a self-administered, anonymous, paper survey. Between October, 2005 and January, 2006, all women who were first-time users of PPCW's online "Hormones with Optional Pelvic Exam" (HOPE) website to obtain HC were shown a link by which they could choose to participate in web-based survey. The surveys were identical aside from their method of dispersment. Completion of the survey implied consent.

First-starts (non-refill appointments) were chosen to reduce the confounding introduced by receiving the education about hormonal contraception multiple times from similar visit types. Women could have used any kind of birth control in the past and could have received services from PPCW in their other programs, but not from the HOPE programs. The clinic women were offered the survey when they were checking out after their appointment and the online women could follow the link at the last page of the website, so both groups of women had been exposed to education regarding the risks and

contraindications to hormonal contraception before they knew about or took the survey. In both groups of women, extensive education about birth control options and the risks and benefits of each method are given. Women in both groups who participated were compensated two movie tickets.

In the clinic, PWOP patients check in at the front desk and are given a contraceptive booklet which has a brief description of all methods PPCW offers and then the specific fact sheet on the method they desire. They fill out a medical history upon check-in which is then reviewed by a nurse. They are weighed and have their blood pressure and height measured. At that point, the desired method of contraception is discussed and instructions are given for use. Providing there are no contraindications, the birth control would be dispensed.

Clinic patients were invited to participate in the survey at the time of check-out. Support staff identified eligible participants by checking the encounter form for a special symbol endorsed by the clinic nurse indicating the patient had participated in the PWOP program. The support staff asked patients if they had a few minutes to fill out a survey for which they would receive two free movie tickets.

On the PPCW website, HOPE patients are first asked to give their credit card information (a credit card is required to complete the transaction). Patients then complete a sexual and contraception history. Following this, women answer comprehensive questions about their past medical history, social history (including tobacco, alcohol, and intravenous drug use and exposure to domestic violence), and family history. They are then requested to provide demographic information. A nurse then reviews the patient's request for birth control and calls the patient to discuss the application. The nurse also

talks about the contraindications to and possible side effects of HC and when to call a provider about dangerous complications that may occur from HC. Women can also browse standardized PPCW fact sheets regarding contraception that are available online through the Online Health Center (30). The patient must get a blood pressure measurement from a pharmacist or provider and fax it to PPCW. If there are no contraindications, they receive one month of HC. At the end of this month, they must fax another blood pressure measurement, and provided that this measurement is within normal limits, they are then prescribed a year's supply of HC.

Questionnaire

The questionnaire was designed to identify knowledge of the risk factors of HC and collect demographic data about the women using the services. The paper survey and the web-based survey were identical in content to one another, aside from one question ("Why did you go into Planned Parenthood instead of using Planned Parenthood's online services to obtain hormonal contraception?") (Appendix A). Aside from this question, the two surveys differed only in the method of dispersal and environment in which the subject entered information.

To address the primary hypothesis that the knowledge of the risks of HC is not equivalent between the online and clinic populations, two knowledge questions were presented first. The questions were developed by the authors using PPCW's material regarding risks of HC, using their wording whenever possible. These risks are generally agreed upon criteria for contraindications to use and potential dangerous complications from HCs, using PPFA, FDA, and WHO consensus information (17-20).

Question 1 asks the participants to identify the correct contraindications to HC from a list of 11 possible choices (Table 1). Seven out of the 11 are actual contraindications (e.g. “blood clots in veins or arteries”). The other four are not contraindications related to HC (e.g. “iron deficiency anemia”). These were put into the survey to discriminate between the participants’ higher level of knowledge of the risks of HCs and their ability to guess correctly. Question 2 asks the subjects to correctly identify potential dangerous side effects (e.g. “red, swollen, or painful leg or arm”) of HC from a list of 10 possible side effects (Table 2). Of the 10, five are actual potential dangerous side effects of HC, and five are not dangerous potential side effects (e.g. “joint pain”).

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.

To assess whether the two populations were similar, basic demographic information was collected. Information about the main form of contraception in the past year was also collected to ascertain potential confounding by previous contraception use. Additional questions were asked about Pap smear history, decision regarding use of the either the website or clinic, satisfaction with the online or PWOP service, and whether or not their insurance covered birth control. Questions were either true or false, multiple choice, or 5-point Likert scale.

To improve clarity and readability, the survey was edited by an employee of the Oregon Department of Human Services (DHS) who creates surveys for DHS and has extensive survey experience. Twenty highly educated people associated with the medical fields (medical students, residents/fellows, faculty, nurses practitioners, and doctors) were asked to take the questionnaire in an ad-hoc validation of the survey questions. There were pre-defined correct and incorrect answers to the knowledge questions and the

survey wording was discussed with these participants to ensure that the questions accurately assessed knowledge of the risks of HC.

Outcomes

A score was calculated for each knowledge question based on the number of sub-questions answered correctly. The two outcomes were the proportion correct out of *all* contraindications or complications (total score) and proportion correct out of the *true* contraindications or complications (final score). The false sub-questions were taken out of the final score as knowledge of actual risk factors of HC was the desired outcome, not the women's test-taking abilities.

Statistical Analysis

A two-sample t-test of equivalence was used to assess whether the mean percentage correct was equivalent between the two populations (31). We took this approach because the scientific hypothesis of interest was that the two groups do not differ, and thus the traditional statistical hypotheses are reversed, i.e. the null hypothesis was that, compared to women receiving health care in the clinic, an online resource would not adequately educate women about HC risk factors. The alternative hypothesis was that the online population had an equivalent knowledge of the risk factors of HC as the clinic population. 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 even one question difference among the

populations was considered harmful. To understand patterns of differences or similarities, further analysis was used to compare the proportion correct on individual sub-questions. A clinically meaningful difference was set at $\geq 15\%$ difference on the upper bound of a 99% confidence interval, to account for multiple comparisons, as Bonferroni adjustment is too conservative for this number of comparisons (32). All analyses were completed using SPSS (version 13.0; SPSS Inc, Chicago, IL).

Chi-square tests were calculated to compare our sample with the overall HOPE population at PPCW and were also used to measure differences in demographic factors between the 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. Age, education, and income were given in ranges (Table 3). The following categorical variables were reduced to dichotomous variables due to low numbers: race/ethnicity (white and not Latina, not white and/or Latina); language (English, not English); health insurance status (yes, no); and main form of contraceptive in the past year (hormonal, not hormonal).

To assess whether the knowledge was equivalent in a demographically similar population, a restricted sub-group of data were analyzed based on age, as it was the major marker of income, education, and health insurance status differences. 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. The middle age groups were chosen, 20 – 24 and 25 – 29, and combined.

The sample size was calculated for the primary outcome of whether clinic patients and online users have an equivalent percentage of correct responses to the knowledge questions. Assuming a conservatively high correlation of 0.75 between answers on a question and an overall proportion of 50% correct for each contraindication or complication question, with 80% power and an alpha of 0.05 for the test of equivalence based on a t-test, 136 subjects were required in each group.

Chapter 3 – Results

Participation

There were 267 users of the HOPE online site during the study period, and 243 completed surveys, for a response rate of 91.0%. A total of 171 clinic surveys were returned, 161 of which were complete. We could not obtain a record of how many first-start PWOP patients were seen during this time. There is only a record of how many total PWOP patients, rather than specifically first-start patients, were seen during that time. Therefore, we cannot calculate an accurate response rate for our questionnaire. Based on the number of total PWOP patients seen during the study period, the estimated response rate was 11.63%. This is an underestimate because many of the women seen at that time were refill patients and were thus ineligible for the survey.

The demographic characteristics differed substantially between the clinic and online groups (Table 3). The two populations differed on all measured demographic variables aside from race (80.7% of the clinic population and 85.6% of the online population was white) and language spoken at home (92.5% of the clinic population and 96.3% of the online population spoke English). Ninety-one percent of the online and

69.1% of the clinic population would recommend the services to a friend or family member.

Table 3. Demographic characteristics among women obtaining prescriptions for hormonal contraception without a pelvic exam at PPCW.

	Clinic (n = 161)		Online (n = 243)		χ^2	p-value
	n	%	n	%		
<u>Insurance</u>						
<i>No</i>	109	68.4	116	48.3	15.549*	< 0.0001
<u>Contraception</u>						
<i>Not Hormonal</i>	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>						
<i>No</i>	143	88.8	232	95.5	6.373*	0.012
<u>Race</u>						
<i>Not White</i>	31	19.3	35	14.4	1.668	0.197
<u>Language</u>						
<i>Not English</i>	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 2yr 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		
\$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

Descriptive Statistics

The study sample (PWOP and HOPE) differed significantly from the general PPCW population (which included 22,052 women at all PPCW clinics and online). Our total study sample was significantly different from the general HOPE population by income (more affluent; $p < 0.0001$), age (older; $p = 0.0371$), education (more highly educated; $p < 0.0001$), and insurance status (less likely to have insurance; $p < 0.0001$), but not race (Table 4). When comparing the PWOP clinic study group and the general PPCW population, without the HOPE online study patients, they also differed by income (more affluent; $p < 0.0001$), age (younger; $p < 0.0001$), education (more highly educated; $p < 0.0001$), and insurance status (less likely to have insurance; $p < 0.0001$), but not by race (Table 5). When the HOPE online study population was compared to the general PPCW population, they too differed by income (more affluent; $p < 0.0001$), age (older; $p < 0.0001$), education (more highly educated; $p < 0.0001$), and insurance status (less likely to have insurance; $p < 0.0001$), but not by race (Table 6).

Table 4. Demographic comparisons of the general PPCW population to the total study population (PWOP and HOPE online, n = 404).

	General PPCW		Total Study Population		p-value
	n	%	n	%	
<u>Insurance</u>	27,661				
<i>No</i>	2,484	9.0	225	55.7	< 0.0001*
<u>Age (yrs)</u>	22,052				
≤ 20	5,674	25.7	85	21.0	0.0371*
20 – 24	8,240	37.7	148	36.6	
25 – 29	4,706	21.0	107	26.5	
30 – 34	1,802	8.2	39	9.7	
≥ 35	1,630	7.4	25	6.2	
<u>Race</u>	28,442				
<i>Not White</i>	5,250	18.5	66	16.3	0.2721
<u>Education</u>	26,637				
< <i>High School</i>	6,865	25.8	38	9.4	< 0.0001*
<i>Completed HS or GED</i>	9,810	36.8	77	19.1	
<i>Some College or 2yr College</i>	5,235	19.7	143	35.4	
<i>College Graduate</i>	4,171	15.7	120	29.7	
<i>Graduate School</i>	556	2.0	26	6.4	
<u>Income</u>	22,052				
<i>Don't Know/empty</i>	295	1.3	55	13.6	< 0.0001*
< <i>\$10,000</i>	13,715	62.1	112	27.7	
<i>\$10,000 – 19,999</i>	6,047	27.4	74	18.3	
≥ <i>\$20,000</i>	1,995	9.1	163	40.4	

* Statistically significant at p < 0.05 level

Table 5. Demographic comparisons of the general PPCW population to the sample of PWOP clinic patients (n = 161).

	General PPCW		PWOP Sample		p-value
	n	%	n	%	
<u>Insurance</u>	27,661				
<i>No</i>	2,484	9.0	44	27.3	< 0.0001*
<u>Age (yrs)</u>	22,052				
≤ 20	5,674	25.7	68	42.2	< 0.0001*
20 – 24	8,240	37.7	66	41.0	
25 – 29	4,706	21.0	18	11.2	
30 – 34	1,802	8.2	6	3.7	
≥ 35	1,630	7.4	3	1.9	
<u>Race</u>	28,442				
<i>Not White</i>	5,250	18.5	31	19.3	0.7952
<u>Education</u>	26,637				
< <i>High School</i>	6,865	25.8	35	21.7	< 0.0001*
<i>Completed HS or GED</i>	9,810	36.8	54	33.5	
<i>Some College or 2yr College</i>	5,235	19.7	48	29.8	
<i>College Graduate</i>	4,171	15.7	22	13.7	
<i>Graduate School</i>	556	2.0	2	1.2	
<u>Income</u>	22,052				
<i>Don't Know/empty</i>	295	1.3	44	27.3	< 0.0001*
< <i>\$10,000</i>	13,715	62.1	56	34.8	
<i>\$10,000 – 19,999</i>	6,047	27.4	32	19.9	
≥ <i>\$20,000</i>	1,995	9.1	29	18.0	

* Statistically significant at p < 0.05 level

Table 6. Demographic comparisons of the general PPCW population to the sample of HOPE online patients (n = 243).

	General PPCW		HOPE Sample		p-value
	n	%	n	%	
<u>Insurance</u>	27,661				
<i>No</i>	2,484	9.0	116	47.7	< 0.0001*
<u>Age (yrs)</u>	22,052				
≤ 20	5,674	25.7	17	7.0	< 0.0001*
20 – 24	8,240	37.7	82	33.7	
25 – 29	4,706	21.0	89	36.6	
30 – 34	1,802	8.2	33	13.6	
≥ 35	1,630	7.4	22	9.1	
<u>Race</u>	28,442				
<i>Not White</i>	5,250	18.5	35	14.4	0.1035
<u>Education</u>	26,637				
< <i>High School</i>	6,865	25.8	3	1.2	< 0.0001*
<i>Completed HS or GED</i>	9,810	36.8	23	9.5	
<i>Some College or 2yr College</i>	5,235	19.7	95	39.1	
<i>College Graduate</i>	4,171	15.7	98	40.3	
<i>Graduate School</i>	556	2.0	24	9.9	
<u>Income</u>	22,052				
<i>Don't Know/empty</i>	295	1.3	11	4.5	< 0.0001*
< <i>\$10,000</i>	13,715	62.1	56	23.1	
<i>\$10,000 – 19,999</i>	6,047	27.4	42	17.3	
≥ <i>\$20,000</i>	1,995	9.1	134	55.1	

* Statistically significant at p < 0.05 level

Equivalence of Knowledge

The overall scores for each population are given in Table 7. The two study populations (PWOP and HOPE) had equivalent total scores on the contraindications to HC (Question 1) and on the warning signs of serious events related to HC (Question 2). A final score was computed by removing the false sub-questions, and the mean percent correct scores improved in both populations. The criteria for the equivalence of the

HOPE online population to the PWOP population was when the 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%). By these criteria, the scores between the groups were statistically equivalent to one another for all comparisons.

Table 7. 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.

Performance on the individual sub-questions was examined to see how the women scored on specific contraindications or complications (Tables 8 and 9). While the knowledge of the two groups was equivalent, it was important to consider the patterns of performance, as the scores were composites of individual sub-questions. Most questions had a high percent correct for each group. The HOPE online population did significantly worse (believed false contraindications were actual contraindications, favoring safety) on three (“thyroid disease,” “irregular periods without heavy bldg,” and “recent abortion”) out of the four false contraindications (Question 1) and the PWOP population did significantly worse on the other (“iron-deficiency anemia”). The PWOP population scored significantly worse on the false complications (Question 2). On the actual

contraindications, the HOPE online population had equivalent knowledge as the clinic patients, except for the “liver disease” contraindication, on which they scored worse than the clinic patients. In contrast, the PWOP population’s scores were less than equivalent on the “migraine with aura,” the “age over 35 years and smokes cigarettes,” and the “hypertension” sub-questions. Again, the PWOP population’s scores were lower than those of the HOPE online population, but only two of the five were statistically significant after controlling for multiple comparisons. The online population had equivalent knowledge on all of the individual symptoms of possible complications of HC.

Table 8. Question 1 Characteristics: “I would not use the Pill, the Ring, or the Patch if I had a history of the following:”

	Correct		Mean Difference	99% [§] Confidence Interval
	Clinic (161)	Online (243)		
Iron-deficiency anemia	0.484	0.568	-0.083	-0.214 [‡] , 0.048
Thyroid disease	0.404	0.374	0.029	-0.099, 0.158 [†]
Irreg periods w/o heavy bldg	0.671	0.617	0.054	-0.073, 0.180 [†]
Recent abortion	0.590	0.539	0.051	-0.080, 0.182 [†]
<i>Blood clots in vessels*</i>	0.919	0.938	-0.019	-0.086, 0.048
<i>Liver disease*</i>	0.826	0.765	0.061	-0.047, 0.168 [†]
<i>Heart attack*</i>	0.901	0.864	0.036	-0.050, 0.122
<i>Stroke*</i>	0.894	0.901	-0.007	-0.086, 0.073
<i>Migraine with aura*</i>	0.702	0.770	-0.068	-0.183 [‡] , 0.047
<i>Age over 35yrs and smoker*</i>	0.652	0.881	-0.228	-0.332 [‡] , -0.125
<i>High blood pressure*</i>	0.783	0.831	-0.049	-0.152 [‡] , 0.054

§ 99% confidence interval used to control for multiple comparisons.

* *Actual contraindications* to using hormonal contraception.

† Online population does not have equivalent knowledge using < 15% difference.

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

Table 9. Question 2 Characteristics: “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:”

	Correct		Mean Difference	99% [§] Confidence Interval
	Clinic (161)	Online (243)		
Nose bleed	0.814	0.856	-0.042	-0.139, 0.054
Nausea	0.317	0.407	-0.091	-0.217‡, 0.036
Dry mouth	0.702	0.691	0.011	-0.111, 0.132
Joint pain	0.665	0.704	-0.039	-0.161‡, 0.083
Bloating	0.652	0.704	-0.052	-0.174‡, 0.071
<i>Severe chest pain or hemoptysis*</i>	0.733	0.774	-0.041	-0.154‡, 0.072
<i>Severe shortness of breath*</i>	0.702	0.761	-0.059	-0.175‡, 0.056
<i>Red, swollen, or painful limb*</i>	0.764	0.802	-0.038	-0.146, 0.069
<i>Sudden, severe headaches*</i>	0.826	0.881	-0.055	-0.146, 0.037
<i>Severe pain in abdomen*</i>	0.857	0.889	-0.032	-0.118, 0.055

§ 99% confidence interval used to control for multiple comparisons.

* *Actual possible symptoms of complications* from using hormonal contraception.

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

Sub-analyses

A sub-analysis was done, limiting the two populations by age, using a one question difference for equivalence (Table 10). In this analysis, the two populations still had equivalent knowledge of the contraindications to use of hormonal contraception. The online group actually had superior knowledge of the complications in the matched population. Within this sub-population of those between 20 – 29 years of age, knowledge of the contraindications/complications of HC does not vary between the two populations after controlling for additional demographic variables, using a multivariable approach.

Table 10. 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)	-0.031	-0.090, 0.029
Question 2	75.71 (84)	83.86 (171)	-0.082	-0.152‡, -0.011

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

Chapter 4 – Discussion

Access to contraception is a difficult challenge for many women. Services that can increase access may have a positive influence on family planning and can result in a reduction in the rate of unintended pregnancy. One possible way to increase access to contraception is to offer prescriptions online to qualified women. A concern about increased access is that women who should not use HC may use it inappropriately. PPCW is the first family planning provider in the United States to offer prescriptions for HC online and provided an opportunity for us to assess the concern that women who do not have an office visit are less informed. In this thesis, we studied the knowledge of the risk factors of HC and found no substantial reason to be concerned.

Population Characteristics

The women who used the online resource to obtain prescriptions for HC were older, more likely to have health insurance, more highly educated, have higher incomes, less likely to be Latina, and more likely to have used hormonal contraceptives in the past year than women who acquired their prescriptions through an office visit without having a pelvic exam. These data show that the population of women who self-select to use an online resource to obtain HC represent a more affluent, educated, and older population than women seeking contraception in general.

The self-selection that occurred with the online population is not unexpected. In addition to preference of method, there are barriers to using computers for many women. Despite the near ubiquity of computers, access is still limited. A credit card is necessary to pay for the online prescription and if one does not have insurance, the prescription ends up being more expensive than visiting the clinic. This is because many of the family planning grants to reduce the cost of birth control are not accepted when obtaining HC from the online service. Privacy issues may also affect women's performance. The different environments may affect how the surveys are taken, for example women may be more candid online in the privacy of their homes, some may find the website more appealing with colors and radio-buttons, or others may find the paper survey easier to read. At this point in time however, it appears that women who are using the online resource are as knowledgeable as women seeing a provider in person to obtain HC.

Equivalence of Knowledge

We found that this online population had equivalent or better knowledge regarding HC contraindications and complications as compared to women who visit a provider in the office, even after adjusting for age, education, income, insurance status, race/ethnicity, language spoken at home, and main form of birth control used in the past year. Both populations of women in our study had high levels of knowledge of the risks of contraception. Mean scores for the PWOP and HOPE populations were 81.10% and 85.01%, respectively on Question 1 and 77.64% and 82.14% on Question 2. This is comparable or higher to other levels of patient knowledge in the medical literature (33,34).

The few studies that have addressed issues of patient knowledge, both online and otherwise, are found in the cardiovascular literature. Patient knowledge scores tested after health care interventions vary greatly in the literature. A group of French hypertensive patients scored approximately 50% correct on questions online about cardiovascular health knowledge (33). Patients tested about their knowledge of heart failure scored 69% correct before given an intensive educational intervention and 85% afterwards (Howie et al. Presented at Am J Crit Care National Mtg, May 2003). Patients taking warfarin scored 72% on a test designed to evaluate their knowledge of the anticoagulant, without having any more education than they already received from their doctors (34).

Small differences between the two populations in the individual knowledge questions were found. The overall scores did not differ; however, the trends in the individual questions indicated that women appeared to overestimate the risk of contraception. The HOPE online population linked more of the false contraindications with contraceptive use while the PWOP clinic population linked more false complications with contraceptive use. Both groups performed similarly on the actual contraindications and complications.

As subjects performed worse on the false contraindications and complications, it appears that women's health knowledge was poor when guessing about contraindications or complications they were not given information about. It may be that the women were overzealous in their determination of what was dangerous, believing nearly everything was hazardous. This hyper-vigilance may be bad in terms of contraception but good in terms of safety. If eligible women believe they are ineligible for HC or women

erroneously believe their symptoms are dangerous and related to HC, they may prematurely discontinue HC. Both situations may lead to fewer women being protected from unintended pregnancy, a condition with higher risks than HC. There may be a negative impact from this perception of risk, as when rates of contraceptive use drops after news media focus on a new risk of HC, such as the 1996 Norwegian and British “pill scare” after the news media focused on venous thrombosis and third-generation progestins, which led to increased rates of unintended pregnancies (35-37).

The women in both populations scored lower on the complications question than they did on the contraindications question. This could be due to the survey itself: poor wording, unclear meaning, or confusing false symptoms. Or, it could be that women receive less education about the warning signs of potentially dangerous complications of HC. Once appropriate women are screened to receive HC, the risk of dangerous side effects are so low that perhaps patients and providers do not focus on possible complications. The lower scores on Question 2 may also be a function of when or how the information is given on the website or during the clinic visit.

Age

In this study, the biggest contributor to the dissimilarity of our populations was the age of our subjects. After controlling for confounders in a sub-analysis of restricted age, women’s scores did not differ. Equivalence or superiority was found in this balanced sub-group of women, which is reassuring. Age was chosen as it appears to be the underlying confounder that accounts for the variation in other variables. For example, if a woman is 16 years old, her education level and income no longer indicate her socio-economic status. Since a major proportion of the clinic population was younger

than 18 years, age becomes the major confounder and renders the other variables less useful. There were not enough data to allow further sub-group analysis to restrict more than one demographic characteristic.

Access to the online HC site may be more difficult for teenagers than other women because of the credit card requirement or privacy issues. Younger people may be less likely to have credit cards. It is also possible that teenagers do not wish to have evidence that they are using family planning services on their home computer. As the use of credit cards becomes more widespread among teenagers, for example using debit cards for allowance payments, questions will be raised about the safety of such an online resource. Teenagers are more likely to be computer savvy than older women so once the barrier of credit card use is removed, safety concerns specific to teenagers must be addressed. Future studies could focus on the question of knowledge of the risk factors of HC within populations of teenagers.

The primary interest of this study was whether this new online technology is as safe as the existing education that women receive in the clinic. Tests of equivalence were used to see if the online population had equivalent knowledge of the risks of HC to the clinic population. We did not specifically set out to understand the mechanism of differences, if found. The observation that the clinic population scored lower raises questions as to whether this group of PWOP women needs enhanced education. Further studies specifically targeting at-risk PWOP women could address this concern. However, the differences in the two populations confound our ability to determine if at-risk women would perform poorly or not.

Strengths

This study provides important information characterizing a population of women who self-selected to use an online resource to obtain HC. As PPCW are 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 Planned Parenthood Federation of America. In addition, this study achieved its pre-defined power by enrolling enough subjects to be able to make statistical inferences regarding equivalency of knowledge.

Our study captured the online population in a comprehensive manner. It is clear by the high response rate online that those results are representative of the women who use the online resource and by the fact that the survey was offered to all first-start patients who obtained HC online. These results give us confidence that the scores of the online patients are representative of the group of women who are using an online resource to obtain HC at this time.

Limitations

There are weaknesses in our study, as with all surveys. Some may have influenced the outcomes, but give us a deeper understanding of who uses an online resource to obtain HC. Our PWOP population of women was not representative of PPCW patients obtaining HC in general. They differ in income, age, education, and insurance status but are of the same race. Therefore the conclusions drawn about our population cannot be generalized to the PPCW patient population. These differences may be related to the fact that our sample was restricted to new-starts in each program,

who differ perhaps from women seeking refills. New hypotheses may be generated from these data that can better address the differences in the populations.

Future studies may want to restrict their study to adults. When the analysis was restricted to women 20 years and older, the populations were still equivalent. Matching women for their demographic characteristics would have been another strategy to strengthen the data, although this would also require much larger sample sizes. Randomization is another approach for making the conclusions more robust, although in this situation it was not possible as women make their own choices about which medium through which they obtain their contraception.

Another limitation of this study is that it is unclear if all eligible women in the clinics were offered the survey. After the initial momentum of giving the survey ran out, the rate of survey delivery slowed. There were periods of time when the surveys were not offered because of lack of movie ticket reimbursements. These may have introduced some unforeseen bias into the clinic population. Selection bias may also have been introduced by who chose to respond. The clinic subjects do not appear to be representative of all the HOPE patients who use the clinic. Furthermore, the choice of movie tickets as incentives may have selected towards a particular group of women.

Since these data do not provide insight into the expected knowledge of lower income, younger women with less education using an online resource, conclusions cannot be generalized to these at-risk women. It is possible they would also have equivalent knowledge of the risk factors of HC if they used an online resource but we do not have the data to make that assertion.

Chapter 5 – Summary and Conclusion

The use of computer-assisted patient education has increased in the last decade. Computers have been integrated into schools and businesses, but not as well incorporated into health care settings. A 2005 review of multimedia patient education concluded that there is a paucity of studies investigating computer-assisted patient education in the medical literature (38). This may be due to a lack of confidence in computer education, an over-valuing of face-to-face contact with a provider, low reimbursements for patient education, or licensure laws. Computer-assisted patient education can be an appropriate technology for increasing access to contraception. HC are safe, effective, and well-studied drugs that may achieve over-the-counter status in the near future (4,6,10,14). Computer-assisted patient education and online prescriptions may be a valuable bridge until that occurs.

A major hurdle to online access is ensuring that women receive equivalent care as they would receive in-person. Our study demonstrated that the current online population at PPCW has equivalent knowledge of the risk factors of HC. A comparison of the demographics of the two study populations shows that the online group is older, more affluent, and has a higher education level. This clearly has implications for expanding online access to groups who are not currently using the online service. Before targeting the program to other populations, future study is needed to determine their knowledge levels. Designing an online system that assures an equivalent level of knowledge would go a long way toward helping to safely increase contraception access for women.

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Appendix A. Paper survey given to the PPCW PWOP women to assess knowledge of HC contraindications and complications.



CENTER for WOMEN'S HEALTH
OHSU



Planned Parenthood
of the Columbia/Willamette

We would like to evaluate the safety of our online services. We would appreciate your taking a few minutes to answer the following questions. Your answers will remain anonymous.

Thank you for your help.

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

CONDITION	TRUE	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		

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*):

SYMPTOM	TRUE	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		

How likely are you to have a Pap smear within the next year?

- Very Likely
- Maybe
- Not Likely

When did you last have a Pap smear?

- I've never had a Pap smear.
- Within the last year.
- Between 1 and 2 years ago.
- Between 2 and 3 years ago.
- Longer than 3 years ago.

Why did you go into Planned Parenthood instead of using Planned Parenthood's online services to obtain hormonal contraception? (Mark all that apply).

- More convenient
- Less expensive
- Faster service
- Did not know about online services
- Did not want a pelvic exam
- Did not want a complete examination
- Confidentiality issues
- Difficulty seeing a health care provider because of distance
- Parental issues
- Other (please specify): _____

I would recommend the Pills with Optional Pelvic Exam (or HOPE) to a friend or family member. (Mark only one).

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

How did you hear about the PWOP/HOPE program? (Mark all that apply).

- Planned Parenthood website
- Planned Parenthood clinic/health center
- A different website
- Newspaper
- Radio ad
- Internet search engine (please indicate search phrase) _____
- School
- From a friend
- From a health care professional
- Other: _____

Do you have health insurance?

- Yes
- No

IF YES, does your health insurance cover birth control?

- Yes
- No
- Don't know

What has been your *main* form of contraception in the past year (*indicate with a 1*)? If you used any *secondary* (back-up method) of contraception in the past year, please indicate that also (*mark with a 2, 3, etc*).

- Nothing
- Oral contraceptives (the Pill)
- Condoms
- Depo Provera
- Cervical caps or diaphragms
- Emergency Contraception
- Intrauterine device (IUD)
- NuvaRing (the Ring)
- Ortho-Evra (the Patch)
- Spermicidal foams and creams
- Female condoms
- Abstinence
- Rhythm method
- Other: (please indicate which type) _____

The following questions will help us to insure that the opinions of different people are represented in this study.

How old are you, in years?

- 16 or younger
- 17 – 19
- 20 – 24
- 25 – 29
- 30 – 34
- 35 – 39
- 40 or older

Would you describe yourself as Spanish, Hispanic or Latina? (*Mark only one*).

- Yes
- No

How would you describe your race? (*Mark all that apply*).

- American Indian or Alaskan Native
- Asian
- Black or African-American
- Native Hawaiian or other Pacific Islander
- White
- Multi-racial
- Other

What language do you speak at home?

- English
- Spanish
- Other

What is the highest grade or level of school you have completed? (*Mark only one*).

- Less than high school
- Completed high school
- High school diploma or GED
- Some college
- Completed vocational/technical training or a 2 year degree program
- College graduate (e.g., B.A. or B.S.)
- Graduate school

What kind of health insurance do you currently have?

- None
- Medicare
- Medicaid (OMAP, Oregon Health Plan (OHP), Care Oregon, Washington Medicaid)
- Private health insurance through your own, your spouse, or a parent's job
- Other

What was your total household income (income from all sources including child support, alimony, disability, SSI, unemployment) before taxes, in 2004? *Please remember your answers are confidential.*

- Less than \$5,000
- \$5,000 to \$9,999
- \$10,000 to \$19,999
- \$20,000 to \$39,999
- \$40,000 to \$74,999
- \$75,000 to \$99,999
- \$100,000 or more
- Don't know

Please share your comments, if any, in the text box below:
