Effectiveness of Breast Self-examination Prompts on Oral Contraceptive Packaging

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Budground. The purpose of this study was to determine if a breast self-examination (BSE) "prompt" on oral contraceptive pill (OCP) packages would improve the frequency and timing of BSE among women who use OCPs.

Ithods. Women between 13 and 40 years of age who were initiating, restarting, or continuing use of OCPs completed a baseline survey that assessed health behavor and practices. All received BSE education and then were randomized to take either OCPs with a BSE grompt or regularly packaged OCPs (without BSE grompt) for three cycles. Three months later, subjects completed a follow-up survey that assessed BSE frequency and timing. A telephone survey of randomly seated subjects conducted 6 months after the baseline survey assessed BSE compliance after discontinuation of meprompt.

ludts. Of the 907 subjects at baseline, 49.3% perimed BSE monthly but only 24.5% performed BSE using the correct time of the menstrual cycle. Among the biects who never performed BSE prior to the study, 43% of prompt subjects and 36.4% of the educationthy subjects began BSE by the 3-month survey. thong subjects who performed BSE less than once per

th year, it is estimated that 182,000 women in the lited States develop breast cancer.¹ Despite these iming figures, there is no single "ideal" screening test

mitted, revised, July 11, 1995.

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1996 Appleton & Lange

ISSN 0094-3509

month at baseline, 50.9% of prompt subjects and 45.5% of education-only subjects increased the frequency of BSEs to a monthly basis by the 3-month survey. More women performed BSE during the correct time of the menstrual cycle at the 3 month follow-up survey (68.1% prompt, 62.2% education only) and 6-month survey (57.4% prompt, 48.9% education only) when compared with the baseline survey (24.7% prompt, 24.1% education only). Ninety-one percent of women in this study expressed a preference for a BSE prompt on OCP packaging.

Conclusions. An increased frequency of BSE was observed when women were exposed to an OCP package prompt, particularly for women who at baseline were already partially compliant with performing monthly BSE. A small but significant improvement was observed for correct BSE timing and this effect continued after the prompt was removed, although at a reduced level. The innovative BSE prompt was overwhelmingly well received by women in this study.

Key words. Cancer; breast; breast self-examination; health promotion; reminder systems. (*J Fam Pract 1996; 42:43-48*)

that is both readily available and sensitive for women of all age groups. Mammography, clinical breast examination (CBE),² and breast self-examination (BSE)³ collectively contribute to the breast cancer screening strategy. Each method differs by the manner of disease identification, but all depend ultimately upon patient motivation and compliance.

Mammography, when performed and interpreted properly, is relatively sensitive⁴ and is the recommended primary screening test for middle-aged and elderly women.⁵ The positive predictive value of mammography is highest for women 50 years of age or older and for women 40 years of age or older with a family history of breast cancer.⁶ Mammography adds additional expense to screening, exposes the patient to low levels of radiation, and may be perceived by patients as uncomfortable. Clinical breast examination also entails additional cost and inconvenience for the patient. The sensitivity and specificity vary depending on the expertise of the examining clinician.^{7,8} Both an annual screening mammogram and an annual clinical breast examination are recommended by the American Cancer Society and the National Cancer Institute for all asymptomatic women 50 years of age or older.⁹

Breast self-examination is simple, safe, convenient, inexpensive, and may be performed frequently. Tumors missed by CBE and mammography and tumors that develop during the interval between these primary screening tests may be detected by BSE.³ Women who perform BSE have their conditions diagnosed at an earlier disease stage and have increased survival rates when compared with women who do not perform BSE.^{10,11} In addition, most breast cancers (80%) are detected by patients.¹² However, the efficacy of BSE remains suspect and extremely variable.^{12–16} A monthly BSE is recommended by the American Cancer Society¹⁷ and the National Cancer Institute.¹⁸

Unfortunately, BSE compliance by women has been less than ideal.^{3,19} The main reason women do not practice monthly BSE is forgetfulness.²⁰ Motivational or BSE prompts using postcards,^{21,22} calendars,²³ calendar stickers,²¹ patient education materials²⁴ and instructions,²⁵ and telephone calls²² have been variably successful and are generally dependent on continuation of the prompt.²¹ When compared with BSE education and clinician demonstration of BSE, the BSE prompt is the most effective method of increasing the frequency of BSE.²⁶ Prompts that have been previously studied have involved the increased costs of materials, postage, and health care provider time.^{19–23} Furthermore, few women (20%) perform BSE during the optimal phase of the menstrual cycle, which is during the first week after menses.^{27,28}

Health warning labels are federally mandated for tobacco and alcohol products to educate and protect consumers. Health warning labels to prevent adverse events may also be found on nonprescription drugs or placed on prescription pharmaceutical packaging. However, health promotion messages on pharmaceutical products are novel. Such messages could stimulate healthy behaviors at almost no cost to society.

The purposes of this study were to (1) determine if the use of a BSE prompt on oral contraceptive pill (OCP) packages would be recalled by subjects exposed to the prompt; (2) determine if the use of a BSE prompt on OCP packages would improve the frequency of BSE; (3) determine if the placement of the BSE prompt would improve the appropriate timing for BSE during the menstrual cycle, and (4) determine women's attitudes toward a BSE prompt on OCP packaging.

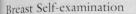
Methods

Patient Population

Women between 13 and 40 years of age were recruited from seven health care sites including The Medical College of Georgia Family Medicine Center and Student Health Service and the Richmond County Health Department, Augusta, Georgia; Burke County Health Department, Waynesboro, Georgia; Gilbert Health Center. University of Georgia, Athens, Georgia; Brookdale Hospital Medical Center Adolescent Gynecology Clinic. Brooklyn, New York; and Adolescent Clinic, Schneider Children's Hospital, Long Island Jewish Medical Center. New Hyde Park, New York. The inclusion criteria were that the subjects be female, 13 years of age or older, and initiating, restarting, or continuing OCP use. The exclusion criteria were the surgical absence of both breasts, a physical handicap that made BSE impossible, pregnancy. and a contraindication to OCP use.

Study Design

The study was a multicenter, randomized, parallel group design. Clinicians were blinded to group randomization. Eligible women were asked to participate in a health promotion study, and informed consent was obtained. The consent form was specifically blinded with regard to the intent of the study and the BSE prompt intervention. Subjects completed a 23-item baseline survey that assessed health attitudes, history, risks, behavior, and practices. Five questions assessed BSE knowledge, attitude, and performance, and the remainder were distractor items. A general physical and a pelvic examination were performed, and when determined necessary by the clinician, subjects were taught the technique of BSE. Subjects then received a free three-cycle supply of norethindrone acetate and ethinyl estradiol with ferrous fumarate (Loestrin Fe 1.5/30, Parke-Davis, Morris Plains, NJ) ora contraceptive pills, the package insert, and a general health promotion pamphlet produced by the American Cancer Society that included one section about BSE technique. Subjects were randomized to two intervention groups using a computer-generated randomization code provided by the OCP manufacturer. Two thirds of the randomized subjects comprised the education plus BSE prompt intervention group, hereby noted as the



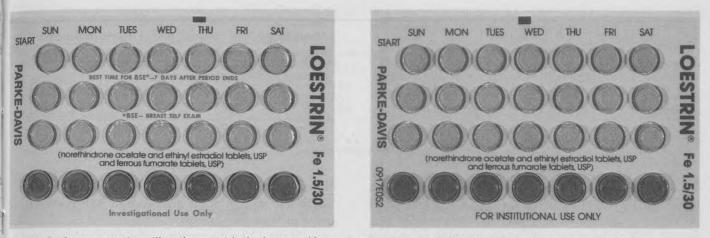


Figure. Oral contraceptive pill packages with the breast self-examination prompt (*left*) and without the prompt (*right*).

"prompt" group. This prompt group received OCP packages that included the statement "best time for BSE*—7 days after period ends, *BSE—Breast Self Exam" printed beneath the first week (eg, first row) of pills (Figure). The remaining one third of randomized subjects served as the education-only group. They received the regularly marketed pill product that did not include a BSE prompt.

All subjects returned in 3 months and completed a 24-item follow-up survey. The survey assessed compliance with BSE and focused on BSE and the prompt. For comparative purposes, the specific BSE questions from the baseline survey were repeated on the 3-month follow-up survey. Subjects who completed the 3 months of OCPs and the two surveys received a complimentary 3-month supply of OCPs without the BSE prompt for their participation in the study. Three months after the follow-up survey, randomly selected subjects completed a short eight-item telephone survey incorporating the same specific BSE questions to assess BSE compliance.

Statistical Analysis

Performance of BSE was defined as a voluntary, manual palpation of each breast and was self-reported. The reported frequency of performance of BSE at each survey was classified as monthly, partial (less than once a month), or never. The primary outcome measure was the proportion of women who performed monthly BSE, as reported on the baseline, 3-month follow-up, and 6-month surveys.

Comparison of demographic characteristics between the two groups was performed using the t test for continuous variables if the assumption of normality was reasonable; if not, the Wilcoxon rank sum test was used. Distributions of categorical variables were compared between the groups using the Stuart-Maxwell, Cochran-MantelHaenszel, Mantel-Haenszel, and McNemar chi-square tests.

Results

Baseline surveys were administered to 907 women, of which 606 were assigned to the prompt group and 301 to the education-only group. Patient demographics showed that the mean age of subjects in the education-only group was 23.7 (standard deviation [SD], 3.98) years and was 24.0 (SD, 4.56) years for the prompt group (P=NS). Racial distributions were not significantly different between the two groups: 76.0% white, 20.1% black, and 3.8% other among the prompt group, and 77.6% white, 18.4% black, and 4.0% other among the education-only group. The highest education level achieved was reported as high school (22.0%), university (59.3%), and postgraduate level (17.4%). The median level of education achieved was 1 year of college for both groups (P=NS). A family history of breast cancer was reported by 5.5% of subjects in the total population.

At baseline, 49.3% of the total subjects enrolled in the study had performed BSE at least once during the previous 3 months, whereas 21.5% had never performed BSE. Only 14% of subjects reported not knowing how to perform BSE. Of the 907 subjects enrolled in the study, 722 completed the three cycles of oral contraceptive pills dispensed. The most common reasons for not completing the study were adverse OCP side effects, loss to follow-up, and no further desire to continue oral contraceptive pills. Approximately one half (51.7%) of the 484 subjects who received the prompt recalled seeing the prompt. Eleven (4.6%) of the 238 subjects in the education-only group stated that they saw the BSE prompt.

BSE compliance data for the 819 women who responded to the BSE frequency question at baseline are

	Baseline		3-Month Survey		6-Month Survey	
BSE Frequency	Education Only, % (n=301)	Prompt, % (n=606)	Education Only, % (n=301)	Prompt, % (n=606)	Education Only, % (n=40)	Promp (n=8
Never	34.4	33.9	34.3	33.1	33.3	31.3
Partial*	31.5	26.7	22.1	21.8	35.9	22.
Monthly [†]	34.1	39.4	43.7	45.0	30.8	45

Table 1. Breast Self-examination (BSE) Frequency for the Entire Study Sample
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*Performs BSE less than once per month

+Performs BSE at least once a month.

NOTE: There were no significant differences between the education-only group and the prompt group.

listed in Table 1. At the baseline and at the 3-month follow-up survey, there were no significant differences between the groups with respect to subjects who performed BSE. However, a greater percentage of women performed monthly BSE at the 6-month survey in the prompt group than in the education-only group (45.6% vs 30.8%). When only the first 3 months of the study were considered (Table 2), significant BSE frequency improvement was observed for both the education-only group (P=.002) and the prompt group (P=.012).

A subset of 219 study subjects, consisting of those in the prompt group who recalled the prompt and who took all three cycles of pills, was selected to realistically represent the effect of the prompt on BSE compliance. Comparable education-only subjects (202) were chosen by excluding those who had not taken all three cycles of pills, who erroneously reported noticing the prompt, or who had not reported BSE frequency at the two surveys. At the 3-month follow-up survey, 48.0% of education-only subjects and 54.8% of prompt subjects reported monthly BSE (Table 3). The change in BSE frequency was significant for both the education-only group (P=.001) and the prompt group (P<.001): 36.4% of the women in the education-only group and 40.3% of those in the prompt group who never performed BSE at baseline improved to

Table 2. Breast Self-examination (BSE) Frequency Results of Baseline and 3-Month Follow-up Survey for the Entire Study Sample

BSE Frequency	BSE Frequency at 3-Month Follow-up			
at Baseline	Never, %	Partial*, %	Monthly†, %	
Education-only group‡				
Never $(n=75)$	61.3	17.3	21.3	
Partial* $(n=78)$	25.6	30.8	43.6	
Monthly \uparrow (n=80)	12.5	16.3	71.3	
Prompt group§				
Never $(n=157)$	60.5	21.7	17.8	
Partial* $(n=120)$	24.2	30.8	45.0	
Monthly \dagger (n=184)	10.3	15.8	73.9	

*Performs BSE less than once per month.

+Performs BSE at least once a month.

⁺ Baseline vs follow-up for BSE education-only group: $\chi^2 = 12.25$, df=2, P=.002. §Baseline vs follow-up for BSE prompt plus education group: $\chi^2 = 8.92$, df=2, P=.012. either a partial or monthly BSE frequency at follow-up There was no significant difference in BSE performanc between these two groups.

Of the 122 subjects who were randomly selected to receive the 6-month telephone survey, 106 subjects (3) education only, 70 prompt) answered the BSE frequenc question on all three of the surveys. Eleven of the 10 education-only subjects (57.9%) and 9 of the 25 promp subjects (36.0%) who never performed BSE at baseline reported performing BSE on a partial or monthly basis a the 6-month survey. The analysis was repeated for the subset of subjects in the telephone survey group who recognized the prompt (Table 4). Results for this group were very similar to those of the entire telephone surve group.

At baseline, 24.1% of education-only subjects and 24.7% of prompt subjects (P=NS) were performing BSI during the correct phase of the menstrual cycle. At the 3-month follow-up, 62.2% of education-only subject and 68.1% of prompt subjects were correctly timing BSE (P=NS). There were also dramatic changes in the proportion of subjects correctly timing BSE within the promp and education-only groups from baseline to 6-month

Table 3. Breast Self-examination (BSE) Frequency Results for Baseline and 3-Month Follow-up Surveys for Patients Who Recognized the Prompt

BSE Frequency	BSE Frequency at 3-Month Follow-up			
at Baseline	Never, %	Partial*, %	Monthly†,%	
Education-only group‡				
Never $(n=66)$	63.6	15.2	21.2	
Partial* $(n=66)$	22.7	31.8	45.5	
Monthly \dagger (n=70)	10.0	14.3	75.7	
Prompt group§				
Never $(n=72)$	59.7	20.8	19.4	
Partial*(n=57)	17.5	31.6	50.9	
Monthly \dagger (n=90)	6.7	7.8	85.6	

*Performs BSE less than once per month.

†Performs BSE at least once a month.

#Baseline vs follow-up for BSE education-only group: $\chi^2 = 13.32$, df=2, P=.001. \$Baseline vs follow-up for BSE prompt plus education group: $\chi^2 = 16.21$, df=2, P<.001.

NOTE: "Prompt recognition group" included subjects who responded to the BSE que tions at the baseline and 3-month follow-up survey, noticed the prompt, and took a three cycles of oral contraceptive pills. Table 4. Results of Breast Self-examination (BSE) Frequency at Baseline and 6-Month Follow-up Surveys for a Sample of the Prompt Recognition Group Surveyed by Telephone (n=71)

- an E - suancy	BSE Frequency at 6-Month Follow-up			
BSE Frequency at Baseline	Never, %	Partial*, %	Monthly†, %	
Education-only group‡				
Never (n=18)	44.4	44.4	11.1	
Partial* (n=8)	25.0	25.0	50.0	
Monthly $(n=9)$	22.2	22.2	55.6	
Prompt group§				
Never $(n=12)$	66.7	25.0	8.3	
Partial* (n=8)	25.0	37.5	37.5	
Monthly \dagger (n=16)	0.0	12.5	87.5	

*Performs BSE less than once per month.

⁺Performs BSE at least once a month. ⁺Baseline vs follow-up for BSE education-only group: $\chi^2 = 2.58$, df=2, P=NS.

Follow-up for BSE prompt plus education group: $\chi^2 = 1.14$, df= 2, P=NS. NOTE: "Prompt recognition group" included subjects who responded to the BSE questions at the baseline and 6-month follow-up survey, noticed the prompt appropriately, and took all three cycles of pills.

follow-up: 48.9% of education-only subjects and 57.4% of prompt subjects who were not using correct timing for BSE at baseline reported correct timing at follow-up; 51.3% of education-only subjects and 61.0% of the prompt group who were not using correct timing of BSE at baseline reported correct timing at 6-month follow-up.

With regard to the BSE prompt, 91.2% of the subjects reported they would like to see a prompt on their packs of oral contraceptive pills, and 79.5% of women who received the BSE prompt indicated that it was help-ful. Of subjects who received the prompt and noticed the prompt, 80.3% stated that the prompt helped remind them to do BSE. More important, 87.8% of subjects stated that the BSE prompt made them feel someone cared about their health. Many subjects (63.0%) thought it was difficult to remember to do BSE on a monthly basis, yet 87.3% felt BSE was either important or very important.

Conclusions

A significant increase in the frequency of BSE was found when women were exposed to a BSE prompt on the OCP package. The increase was particularly noted for women who were initially partially compliant with performing monthly BSE. The prompt improved the regularity of BSE performance for women previously inclined to perform BSE. The prompt also improved the frequency of BSE by 40% for women who had never before performed BSE. Since the focus of the current study was not the education provided by the health promotion pamphlet or the teaching of BSE technique, the observed improvement in BSE compliance demonstrated by women who previously did not perform BSEs was unexpected.

The study included two experimental groups, the education-only group and the prompt group. Each group received BSE education. Although the main interest of the study was the effect of the prompt, the health promotion pamphlet and the BSE education produced a large positive BSE response, which may be attributable to the relatively high educational level of the study participants. Health care providers should continue their educational efforts based on the obvious positive behavioral changes noted in this study. Educational intervention with a simple BSE booklet has been associated with improved breast cancer detection.²⁴ Education is also an important strategy to improve breast cancer screening for women 50 years of age or older, of whom only 45.1% have annual mammography and only 56.9% have an annual clinical breast examination.29

The 6-month telephone survey found an expected decrease in frequency of monthly BSE performance after the removal of the prompt. However, this level of BSE frequency observed at this time was greater than at baseline. It is unclear how long the 3-month prompt effect would continue after its removal, or whether the effect of the prompt would diminish over time if continued.

Significant changes were observed for performance of BSE during the optimal phase of the menstrual cycle for both groups. At the conclusion of this study, the percentage of women performing BSE during the correct time was more than twice that for women at the initiation of the study. Appropriate timing for performing BSE implies that fewer women would seek medical consultation for what otherwise may be benign premenstrual fibrocystic changes. Patient anxiety and inconvenience, medical costs, and clinician time may be minimized by prompting women to perform BSE at the correct time during the menstrual cycle.

The BSE prompt was overwhelmingly well received by subjects. The majority of women liked seeing a BSE reminder on the pack of oral contraceptive pills and thought the prompt helped them to remember to perform BSEs. Three fourths of the women who received and noticed the prompt indicated that it was responsible for reminding them to perform BSEs. In addition, a majority of the women reported that the prompt made them feel that someone cared about their health.

This study has established an innovative health promotion vehicle for preventive medicine. The positive health prompt, as opposed to traditional negative health warning labels on tobacco, alcohol, and pharmaceutical products, successfully induced behavioral changes. The Food and Drug Administration should consider implementing other positive prompts on pharmaceutical packaging to improve health care. Such a health promotion opportunity could target other medical problems with a minimal expenditure of funds.

Several limitations of the study must be acknowledged. First, the duration of the study was brief and the moderate BSE prompt effect could likely diminish over time. The study also targeted young women who are at less current risk for breast cancer compared with an older population. Although the prompt vehicle was ideal for the younger age group, their perception of breast cancer susceptibility may have minimized BSE performance. Finally, the BSE prompt was not readily detected by all women. Only 51.7% of subjects exposed to the BSE prompt recognized the prompt. The prompt message was small and conservative in content, in keeping with traditional FDA labeling policies. A more recognizable BSE prompt could be easily developed with the help of focus groups and its efficacy verified thereafter by eye-tracking studies.³⁰ A more visible prompt could improve the overall reported frequency for BSE performance reported in this study.

Acknowledgments

Financial support was provided by Parke-Davis, Morris Plains, New Jersey. Barbara Miller, Bena Clary, Jan Seals, Alice Taylor, Elizabeth Crans, and Tracey Barton helped prepare the manuscript.

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