A Randomized Study of Cancer Screening in a Family Practice Setting Using a Recall Model

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A randomized controlled study that evaluated a recall system and patient education material by mail in 178 asymptomatic female family practice patients aged 50 to 69 years showed no effect on the proportion of patients who had cancer screening tests (P = .20) and a significant adverse effect on the mean number of tests performed (P = .05) after 4 months. In a subgroup of previous compliers (those who had one or more tests 12 months before the study), however, there was a lower proportion of patients receiving one or more tests (P = .019) with a lower mean number of tests (P = .007) than previous compliers in the control group. Recall strategies for cancer screening tests need to be more extensively studied in the United States before they are routinely adopted in family practice. **J Fam Pract 1990; 30:537-541.**

The poor performance of cancer screening has been previously documented by Batista,[1] Woo et al,[2] and the American Cancer Society (ACS)[3] in its "Survey of Physicians' Attitudes and Practices in Early Cancer Detection." More recently, the 1987 National Health Interview Survey (NHIS) Supplement on Cancer Control,[4] a cross-sectional study of 5723 adults, confirmed low rates of cancer screening in the United States. Even in practices that aggressively screen adult patients at each office visit, as many as 50% of preventable cancers escape early detection.[5] A number of methods have been proposed to increase the performance of screening tests, with limited to modest success (Table 1).

Uncontrolled studies regarding cancer screening tests such as Papanicolaou tests, fecal occult blood tests, and breast screening in the United States, Britain, and Scandinavia have noted variable response rates to an invitation to screening, ranging from 38% to 80%.[18–29] There have been only a few controlled studies evaluating recall systems for cancer screening tests. In 1979 a controlled Kaiser Permanente health maintenance organization study showed a 40% increase in compliance with an invitation to multiphasic screening that included mammography, sigmoidoscopy, and Papanicolaou testing.[30] In a controlled study, Thompson et al[18] evaluated multiple interventions to increase patient compliance with fecal occult blood testing and found a reminder postcard to be the most effective measure, increasing compliance by 25%. Recently, McDowell et al[31] in a controlled study in Canada showed that a mailed reminder increased Papanicolaou testing by 12%.

With the exception of breast self-examination,[32] studies evaluating the impact of printed patient education material on patient compliance with cancer screening tests have been limited and primarily focused on fecal occult blood testing. In Great Britain, Hardcastle et al[20] found patient education material and a personalized letter of invitation by the physician to result in a 47% patient response to fecal occult blood testing, compared with a 38% response rate with a personalized letter alone. Recently, other British studies[6,33] have shown that educational material presented with a letter of invitation to have fecal occult blood testing has either no effect or sometimes an adverse effect on patient compliance.

The purpose of the study reported here was to determine whether a letter recalling patients for a battery of cancer screening tests as recommended by the American Cancer Society, incorporating patient education material,

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TABLE 1. METHODS TO INCREASE THE PERFORMANCE OF SCREENING TESTS

"Opportunistic" screening, or physician screening at each patient visit[1,6,7]
Reminders initiated by nurses[8] or other paramedical personnel[7] to screen at each patient visit
Computer-generated reminders[9] to assist in flagging the chart for tests due at each patient visit
Screening flow sheet on the chart to be used at each patient visit[10–12]
Chart audit to measure a physician's performance in screening[13]
Patient[14–17] and physician[13,17] education programs regarding screening
Recall of patients by telephone or by mail for screening tests[18–29]

resulted in a significant increase in the number of cancer screening tests performed and the proportion of patients having cancer screening tests when compared with a control group.

METHODS

A controlled study involving female patients aged 50 to 69 years was conducted at the ambulatory program of a midwestern university family practice unit. All participating physicians had established practices at this site for over 10 years. The study was approved by the university's human subject review process.

Based on a chart audit, patients who were symptomatic for the cancers being screened and who had previous cancers diagnosed were excluded from the study before randomization. Two hundred twenty patients were then assigned by a computer-generated random number to two groups, intervention (n = 116) and control (n = 104). The initial power calculation was 0.90 with an alpha of 0.05, assuming a 50% compliance for the intervention group and a 30% compliance for the control group. The investigators inadvertently did not consider excluding inactive patients until after randomization and after the study had already begun. Forty-two patients were determined to be inactive, ie, had not been seen in the clinic for 2 years or more as determined by chart audit. The total number of active and eligible patients remaining was 178 patients with 102 patients in the intervention group and 76 patients in the control group.

All of the participating physicians agreed to use American Cancer Society guidelines. The intervention group received a personalized letter, signed in a blinded fashion by the patient's personal physician. The letter was sent about 1 month before the due date of the tests and included the physician's recommendation for specific cancer screening tests: fecal occult blood test, digital rectal examination, sigmoidoscopy, pelvic bimanual examination (except in patients with hysterectomy and bilateral salpingo-oophorectomy), Papanicolaou smear (except for patients with total hysterectomies), breast examination, and mammography. In addition, patient education material was incorporated that gave (1) the patient's general risk for the cancers to be screened, (2) the rationale for individual cancer screening tests, and (3) the cost and risks of the tests. A second recall letter, which included patient education material, was mailed 4 weeks after the first letter to enhance patient response as suggested by Fink et al.[29]

The control group of patients continued to receive their usual care. The physicians remained blinded to the individual patient's status throughout the study.

A second chart audit to determine compliance was conducted 4 months after the tests were due in both the intervention and control groups. The 4-month interval was used rather than a longer interval to avoid diluting the influence of the intervention.

For nominal and ordinal variables, chi-square was used to test significance except when 2×2 contingency tables had cells less than 5, then Fisher's exact test was computed. For interval variables, Student's *t* tests were used to test significant differences. The one-tail significance level was set at $\leq P = .05$.

RESULTS

The characteristics of the intervention and control groups were similar at baseline and are given in Table 2. The intervention and control groups were similar in relation to (1) age ($P = .19$), (2) number of chronic medical problems ($P = .99$), (3) number of screening tests the previous year ($P = .61$), (4) number of office visits the previous year ($P = .84$), (5) usual method of payment ($P = .33$), and (6) attending physician ($P = .94$).

At 4 months 39.3% of all patients had received one or more cancer tests. The intervention group actually had significantly fewer mean number of tests than the control group (Table 3); however, the proportion of persons with one or more tests did not significantly differ between the intervention group (35.3%) and the control group (44.7%). There were no significant differences for any single type of test, although the proportion of the intervention group receiving the tests was consistently less than the proportion of the control group. The most frequent tests were the breast examination and pelvic examination, with the fecal occult blood tests and sigmoidoscopy examination the least frequent.

To evaluate the impact of test compliance in the previ-

TABLE 2. BASELINE VARIABLES FOR RECALL AND CONTROL GROUPS

Variable	Intervention (n = 102) Mean (SD)	Control (n = 76) Mean (SD)	Test of Significance	*P* value
Age	61.44 (5.60)	62.58 (5.78)	$t = 1.32$	.19
Number of chronic medical problems	1.72 (1.93)	1.71 (2.09)	$-t = .02$	.99
Number of screening tests previous year	1.73 (2.29)	1.91 (2.43)	$t = .51$	.61
Number of office visits previous year	2.81 (2.41)	2.88 (2.58)	$t = .21$	.84
Usual method of payment (%)				
Private	59.8	57.9		
Third party (including Medicare)	31.4	31.5		
Health maintenance organization	8.8	6.6		
Medicaid	1.0	3.9	$\chi^2 = 4.53$	.33
Physician				
A	33.3	32.3		
B	17.6	19.7		
C	49.0	47.4	$\chi^2 = .13$	.94

ous year with test compliance at the 4-month audit for the sample, chi-squares were calculated (Table 4). Except for sigmoidoscopy, it is apparent that patients who complied with the cancer screening at the 4-month audit were significantly more likely to have had the test the previous year than those who did not have the tests at the 4-month audit.

Subsequently subjects were analyzed as compliers (those who had any cancer screening tests 12 months before the study began) and noncompliers (those who had no tests during this period). For the noncompliers in the intervention group, the recall letter and patient education material had no impact (Table 5) on the proportion of patients who had a cancer screening test or on the number of tests during the 4-month postintervention (study) period. For the compliers in the intervention group, the intervention had a significant negative impact (Table 5) on the proportion of patients having one or more cancer screening tests and on the number of tests performed when compared with the control group during the 4-month postintervention period.

For the sample, one or more chronic medical problems were present in 68% of the subjects, with the remainder free of chronic medical problems. At the 4-month audit the presence or absence of chronic medical problems had no impact on the proportion of the persons who complied or did not comply with the cancer screening tests ($\chi^2 = 1.26$, 1 *df*, $P = .26$).

TABLE 3. FOUR-MONTH AUDIT OF INTERVENTION (n = 102) AND CONTROL (n = 76) GROUPS

	Intervention Percent	Control Percent	Test of Significance, χ^2	*P* Value
One or more tests	35.3	44.7	1.63	.20
Breast examination	29.4	40.8	2.50	.11
Pelvic examination	26.5	36.8	2.19	.14
Papanicolaou smear	20.6	30.3	2.19	.14
Digital rectal examination	20.6	30.3	2.19	.14
Mammogram	18.6	28.9	2.62	.11
Fecal occult blood test	15.7	26.3	3.04	.08
Sigmoidoscopy	1.0	5.3	—	.64*

Mean number of tests: intervention group, 1.32 (SD = 2.05), control group, 1.99 (SD = 2.43), t = 1.97, P = .05.
**Fisher's exact test.*

TABLE 4. CANCER TESTS FOR THE SAMPLE AT THE 4-MONTH AUDIT RELATED TO COMPLIANCE DURING THE PREVIOUS YEAR

Previous Year Tests	Follow-up at 4 Months		Test of Significance (χ^2)
	No	Yes	
Any test (n)	108	70	
No (%)	68.5	22.9	35.43*
Yes (%)	31.5	77.1	
Breast examination (n)	117	61	
No (%)	82.9	42.6	30.47*
Yes (%)	17.1	63.6	
Pelvic examination (n)	123	55	
No (%)	83.7	45.5	27.57*
Yes (%)	16.3	54.5	
Papanicolaou smear (n)	134	34	
No (%)	88.8	47.7	33.28*
Yes (%)	11.2	52.3	
Digital rectal examination (n)	134	44	
No (%)	83.6	40.9	30.63*
Yes (%)	16.4	59.1	
Mammogram (n)	137	41	
No (%)	85.4	48.8	23.87*
Yes (%)	14.6	51.2	
Fecal occult blood test (n)	142	36	
No (%)	81.7	44.4	20.7*
Yes (%)	18.3	55.6	

*P *value* = .00.

DISCUSSION

This controlled study in a family practice setting found that a recall intervention had no effect on the proportion of patients who had cancer screening tests when compared with patients who were not recalled. Because the study had a low power, however, confirmatory multicenter studies with larger groups of patients should be undertaken to test similar recall strategies in the family practice setting. The low power of this study was attributed to imbalances between intervention and control groups. Such an imbalance can occur when using a simple randomization as recently described by Franks.[34] In retrospect, a blocked randomization should have been considered, which would have balanced intervention and control groups. There was additional imbalance as a result of excluding inactive patients after randomization. Inactive patients should be excluded before randomization in future compliance studies to avoid diluting the effects of the intervention.

The recall letter and patient education material by mail, however, had a significant adverse effect on the mean number of cancer screening tests performed compared with a control group. On further evaluation, the intervention also seemed to affect adversely a subgroup of patients who had previously complied with testing. In some practices with higher baseline rates of screening, such interventions may be particularly counterproductive. Previous compliance history appears to be an important subject variable to be considered in evaluating future compliance strategies.

The design of this study did not allow for a determination of whether the written patient education material had an adverse effect on the recall letter. Future studies on recall models need to consider the effects of adding patient education material to such interventions and also the effects of using increasingly complex patient education material.

In this study patients were asymptomatic for the cancers being screened as determined by chart audit. Perhaps the recall would be more effective if patients who are

TABLE 5. TESTS AT 4 MONTHS, BY INTERVENTION (n = 102) AND CONTROL (n = 76) GROUP, FOR COMPLIERS AND NONCOMPLIERS DURING PREVIOUS YEAR

Compliance Tests at 4 Months	Intervention	Control	Test	*P* Value
Noncompliers* (n)	51	39		
None (%)	80.4	84.6	$\chi^2 = 0.270$	.604
1 or more (%)	19.6	15.4		
Number of tests, mean (SD)	0.63 (1.46)	0.64 (1.65)	$t = .04$	.967
Compliers† (n)	51	37		
None (%)	49.0	24.3	$\chi^2 = 5.516$	.019
1 or more (%)	51.0	75.7		
Number of tests, mean (SD)	2.02 (2.31)	3.41 (2.34)	$t = 2.75$	.007

*Noncomplier—a patient who did not have any tests 12 months before the study began.
†Complier—a patient who had at least one test 12 months before the study began.

symptomatic for the cancers being screened were included in such studies. Some investigators have previously noted that if patients have symptomatic breast disease, they are much more compliant to mammography.[35,36] Blalock et al,[37] however, has noted that symptomatic patients more often intend to participate in fecal occult blood testing, but actual compliance is not increased. Future studies on compliance with cancer screening should further evaluate these asymptomatic and symptomatic subgroups.

Perhaps other variables can be identified in family practice settings that are important in determining a patient's response to a recall intervention. At this time, however, it seems ill advised for family physicians to recall patients routinely by mail for cancer screening tests with or without patient education material until additional studies are performed in the United States.

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