# A Randomized Trial of Direct Mailing of Fecal Occult Blood Tests To Increase Colorectal Cancer Screening

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***Background:*** **Although colorectal cancer screening by using a fecal occult blood test (FOBT), flexible sigmoidoscopy, colonoscopy, or barium enema x-ray reduces the incidence of and death from colorectal cancer, the rate of colorectal cancer screening in the general population is low. We conducted a randomized trial consisting of direct mailing of FOBT kits to increase colorectal cancer screening among residents of Wright County, Minnesota, a community in which colorectal cancer screening was promoted.** ***Methods:*** **At baseline, we mailed a questionnaire about colorectal cancer screening to a random sample of Wright County residents aged 50 years or older who were randomly selected from the Minnesota State Driver's License and Identification Card database (estimated N = 1451). The sample was randomly allocated into three equal subgroups: one group (control) received only the questionnaire, one group received FOBT kits by direct mail with reminders, and one group received FOBT kits by direct mail without reminders. Study participants were sent a follow-up questionnaire 1 year after baseline. We used the responses to the questionnaires to estimate the 1-year change in self-reported screening rates in each group and the differences in the changes among the groups, along with the associated bootstrap 95% confidence intervals (CIs).** ***Results:*** **At baseline, the estimated response rate was 86.5%, self-reported adherence to FOBT guidelines was 21.5%, and overall adherence to any colorectal cancer screening test guidelines was 55.8%. The 1-year rate changes in absolute percentage for self-reported adherence to FOBT use were 1.5% (95% CI = –2.9% to 5.9%) for the control group, 16.9% (95% CI = 11.5% to 22.3%) for the direct-mail-FOBT-with-no-reminders group, and 23.2% (95% CI = 17.2% to 29.3%) for the direct-mail-FOBT-with-reminders group. The 1-year rate changes for self-reported adherence to any colorectal cancer screening test were 7.8% (95% CI = 3.2% to 12.0%) for the control group, 13.2% (95% CI = 8.4% to 18.2%) for the direct-mail-FOBT-with-no-reminders group, and 14.1% (95% CI = 9.1% to 19.1%) for the direct-mail-FOBT-with-reminders group.** ***Conclusion:*** **Direct mailing of FOBT kits combined with follow-up reminders promotes more rapid increases in the use of FOBT and nearly doubles the increase in overall rate of adherence to colorectal cancer screening guidelines in a general population compared with a community-wide screening promotion and awareness campaign. [J Natl Cancer Inst 2004;96:770–80]**

Several effective methods for colorectal cancer screening exist. Results from three randomized trials *(1–3)* and several nonrandomized controlled studies *(4–8)* showed that colorectal cancer screening reduces mortality from the disease, and results from one trial *(9)* showed that screening decreases the incidence of colorectal cancer. Each year in the United States, approximately 148 000 cases of colorectal cancer are diagnosed, and 56 600 people die from the disease *(10)*. National guidelines recommend four methods of colorectal cancer screening for individuals aged 50 years or older who are at average risk for colorectal cancer: an annual fecal occult blood test (FOBT), a flexible sigmoidoscopy every 5 years, a colonoscopy every 10 years, or a double-contrast barium enema x-ray every 5 years *(11–15)*. In one randomized trial *(1,9)*, annual FOBT was shown to reduce colorectal cancer mortality by 33% and to reduce its incidence by 20%. If the other recommended screening methods are at least as effective as an annual FOBT—and if everyone in the United States were to adhere to colorectal screening recommendations over time—then more than 18 800 colorectal cancer–related deaths and 29 600 cases of colorectal cancer could be prevented each year.

Despite this potential benefit, nationwide surveys indicate that the rate of colorectal cancer screening in the general population is low. For example, use of FOBT in the previous year reported by participants in the 1997 Behavioral Risk Factor Surveillance System ranged from 9.2%–28.4% by state (median = 18.0%), and use of proctosigmoidoscopy in the previous 5 years ranged from 15.6%–41.5% (median = 30.0%) *(16)*. The 1998 National Health Interview Survey showed that only 9.8% of women and 19.0% of men aged 50 years or older had undergone screening endoscopy within the previous 3 years and that only 26.1% of women and 28.5% of men had had an FOBT within the previous year *(17)*. The 1999 Behavioral Risk Factor Surveillance System showed that 44.0% of adults aged 50 years or older had had an FOBT or a flexible sigmoidoscopy within the recommended intervals *(18)*. In addition, results of a 1998 Massachusetts study showed that 50.9% of adults aged 50 years or older had used one of the four colorectal cancer screening tests within the recommended screening interval *(19)*. This finding is also mirrored in assessments of more restricted populations, such as managed-care or employee groups *(20,21)*. Taken together, these results suggest that approximately half of the U.S. population lacks the full benefit of colorectal cancer screening.

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*See* "Notes" following "References."

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We conducted a randomized trial to test whether direct mailing of FOBT kits to a general population could increase colorectal cancer screening. The trial took place within the context of the Wright County Colorectal Cancer Screening Project, a county-wide initiative conducted by the Community Health Foundation of Wright County, Minnesota. The initiative included a campaign to educate and raise awareness within the community about colorectal cancer screening through newspaper articles, public service announcements, radio shows, and public presentations; it also made cost-free FOBT kits available in public places to all residents of Wright County who were 50 years old or older. The initiative also included visit planning interventions (i.e., systematic reviews of patient charts before scheduled clinic visits to remind clinicians to discuss screening during those visits) at two of the 11 primary care clinics in Wright County. These two clinics served a substantial minority of the target population. Results of these other initiatives will be reported elsewhere (Yeazel M, Church T, Jones R, Kochevar L, Watt G, Cordes J, et al.: unpublished data); here, we focus on the randomized trial to determine whether such direct mailing efforts are effective in increasing the use of FOBT.

## METHODS

We compared the effectiveness of two interventions that involved the direct mailing of FOBT kits with that of no intervention (i.e., no mailing) among three randomly selected and allocated groups of residents of Wright County, MN. These comparisons were performed against the backdrop of a county-wide campaign promoting colorectal cancer screening. Subjects in each group received a questionnaire at baseline (i.e., before they received the assigned intervention) that asked about their use of colorectal cancer screening tests, and they received a follow-up questionnaire 1 year later that was nearly identical to the baseline questionnaire. The primary outcome of the study was the effect of the assigned intervention on the change in self-reported overall adherence to colorectal cancer screening guidelines. This study was approved by the Institutional Review Boards of the University of Minnesota and the Allina Health System.

### Study Population

Wright County is a nonurban county located just west of the Minneapolis–St. Paul metropolitan area. In 2000, the population of Wright County was 89 986; 19 712 (21.9%) of the county residents were 50 years old or older *(22)*. Wright County residents were eligible for this study if they were at least 50 years old and had a mailing address with a ZIP code that included some part of the county as of January 1, 2000. For the analyses reported in this article, the target population included all eligible subjects who were living in Wright County when they were contacted for the first survey. Because our study addressed screening in a general population, we did not exclude persons who were at high risk for colorectal cancer or in whom colorectal cancer had been previously diagnosed.

### Sampling Method

The Minnesota State Driver's License and Identification Card database contains the name, address, telephone number, and date of birth for all persons who have held a state driver's license or identification card and are not known to be deceased. According to the Federal Highway Administration *(23)*, more than 79% of the Minnesota population of driving age had driver's licenses in 1997; including those with identification cards increased the percentage of the Minnesota population represented by the database, although official statistics are not available. On the basis of the results of the initial mailing for the baseline questionnaire, we estimated that approximately 29.5% of a random sample of 2000 individuals drawn from the 1999 Minnesota State Driver's License and Identification Card database would be ineligible for our study because the listed individual had died, moved out of the county, or had an indeterminate address. We therefore drew a random oversample of 1943 individuals from the database to yield approximately 1500 eligible individuals. The database sample was randomly divided into three equal-sized groups; one group was to receive no direct mailing of FOBT kits (control group), one group was to receive FOBT kits by direct mail without reminders to return the completed tests (FOBT-without-reminders group), and one group was to receive FOBT kits by direct mail with reminders to return the completed tests (FOBT-with-reminders group). The sample size was selected to be large enough to permit post-stratification by age ($<65$ versus $\geq 65$ years old) and sex. The target sample size yields an average of 125 subjects within each age–sex stratum, providing in each pairwise comparison of binomial proportions an 80% power to detect a 10% change in self-reported adherence with a two-sided type I error rate of 5% after adjusting for nonresponsive subjects.

### Direct Mailing of FOBT Kits

All study sample participants ($n = 1943$) were mailed baseline questionnaires. FOBT kits were mailed to participants approximately 2 months after the baseline questionnaire was mailed; only five baseline questionnaires (two from the reminder group and three from the no-reminder group) were returned after the FOBT kits were mailed. Each mailing contained a Hemoccult Sensa FOBT kit (Beckman Coulter, Palo Alto, CA), which consisted of three guaiac-impregnated slides with two specimen windows per slide, several specimen collection sticks, collection tissue, a postage-paid return envelope addressed to the study laboratory located at Buffalo Hospital in Wright County, and a pamphlet providing answers to frequently asked questions about using the FOBT. The mailing also contained a letter signed by one of the authors (M. W. Yeazel) explaining the purpose of the study and urging the recipient to use the test and submit the completed kit to the study laboratory, as well as consent and follow-up forms that were to be completed by the recipient and returned to the study office as soon as possible. The follow-up form allowed participants to indicate that the laboratory should send a copy of their test results to a specific physician. The letter also informed the participant about factors that are associated with a high risk of colorectal cancer and that individuals at such risk might need some other form of screening and should discuss alternative care with their physicians.

We tested two versions of the direct mail intervention. In one version, the participant was to receive no further encouragement or reminding by study personnel to complete and return the FOBT kit; in the other, the participant was reminded to complete the tests after receipt of each FOBT kit. In the latter version of the intervention, after the initial letters and FOBT kits were mailed, nonresponsive participants received a mailed reminder 1

month later, another mailing with a second FOBT kit a month after that, and, 1 month later, a reminder by telephone to complete the test. Participants who indicated during their telephone reminder that they needed another FOBT kit were sent another. Thus, the usual interval from the initial mailing to this final telephone contact was approximately 3–4 months. Because of a mailing error, 49.6% of the participants in the no-reminder group were inadvertently sent the first reminder letter; no further reminders were sent to this group of participants. Note that in the FOBT-with-reminder group, all those not completing and returning the screening kit got this first reminder letter, the second reminder with a new FOBT kit, and a telephone call. Thus, there was still a large difference between the two groups in the extent of reminding that they received. The analysis grouped subjects by their originally assigned intervention, so these participants were analyzed as receiving direct mailing of FOBT with no reminders. The potential effects of this contamination are discussed below.

### Outcome Measures

The primary outcome of this study was the change in self-reported overall adherence, defined as use of at least one colorectal cancer screening test according to guidelines, among residents of Wright County who were at least 50 years old and had been randomly selected to participate in this study. Self-report using mailed questionnaires was chosen for the study endpoint because we did not have access to the medical records of the members of the sample cohort. Information about self-reported use of screening tests was obtained from responses to self-administered questionnaires completed by participants at baseline (i.e., before they received the assigned intervention) and 1 year after baseline. Those questionnaires asked respondents to indicate whether their most recent use of each of the four screening tests was in the past year, between 1 and 5 years ago, between 5 and 10 years ago, more than 10 years ago, or never. For this study, respondents were not asked whether the test they had taken was for screening or diagnostic purposes, because the use of any test eliminated the need for a screening test for the appropriate interval afterwards. The description of each screening test in the questionnaire emphasized the defining characteristics of the test that would help respondents distinguish the different tests from each other and from other medical procedures they might have had. The wording of the colorectal cancer screening questionnaire paraphrased that used by Baier et al. *(24)* and was based on feedback from focus groups. (Questionnaire available at http://jncicancerspectrum.oupjournals.org/jnci/content/vol96/issue10.)

The baseline questionnaire and three reminder mailings for its completion were sent beginning at the end of February 2000, with approximately 4–5 weeks between reminder mailings. The fourth reminder consisted of a brief telephone interview that was conducted with each nonresponder and was limited to the four questions relating to their past use of the four recommended colorectal cancer screening tests. The wording of the core questions in the questionnaires and the telephone surveys was identical. Telephone follow-up for nonresponders to the baseline questionnaires began in late June 2000 and continued until October 2000. Subjects were given no monetary incentives for completion of the baseline questionnaire. The baseline questionnaire, which also included items on demographics, access to health care, previous screening for several chronic diseases, attitudes and beliefs about colorectal cancer screening, and employment type and status, had 55 items on 13 pages and took 10–20 minutes to complete.

Survey procedures at baseline differed slightly from those at the 1-year follow-up. In early March 2001, all participants were mailed an initial 1-year follow-up questionnaire that was nearly identical, both in content and appearance, to the baseline questionnaire; they were also sent a monetary incentive ($2). One week after this initial mailing was sent, we mailed a postcard to all participants that reminded them to return their questionnaires and stated that they would receive a follow-up telephone call within a few weeks if study staff did not receive their completed questionnaire or otherwise hear from them. Most participants returned completed questionnaires within 3 weeks of the initial mailing. Ten days after the reminder postcards were mailed, we began making follow-up telephone calls to participants who had still not returned their completed questionnaires. Telephone interviewers administered the entire questionnaire orally to those who did not return a completed self-administered questionnaire. The 1-year follow-up survey was completed within 9 weeks of the initial follow-up mailing. In general, the administration of the follow-up questionnaire followed the last telephone reminder for the FOBT kit mailing by 6 months. The average time ($\pm$ standard deviation) between the last contact regarding the FOBT kits and our receipt of the completed follow-up questionnaire was 9.3 ($\pm$1.1) months for the FOBT no-reminder group and 7.1 ($\pm$2.1) months for the FOBT-with-reminder group.

The primary outcome of the study was the change in overall self-reported adherence to screening guidelines. Adherence to the colorectal cancer screening guidelines for a specific test was defined as a self-report that the participant had had an FOBT within the previous year, a flexible sigmoidoscopy or barium enema x-ray within the previous 5 years, or a colonoscopy within the previous 10 years. Overall adherence was defined as adherence to any of these tests. The change in overall adherence rates between baseline and the 1-year follow-up within a treatment group was the primary outcome of interest, and differences in these changes were the primary measures of treatment effect. To estimate the effects of the interventions, we compared the change in self-reported overall adherence among the control group with that among the two groups that received the direct mail FOBT kits, and we compared the change in self-reported overall adherence among the group that received FOBT kits with reminders with that among the group that received FOBT kits without reminders. These comparisons were chosen in part because they are independent of each other, whereas groupwise comparisons are structurally dependent. The former comparison examined whether direct mailing of FOBT kits provided an improvement in overall screening adherence compared with that resulting from the colorectal cancer screening promotion already being done in the county; the latter comparison was to examine whether reminders by direct mail enhanced any effect of direct mailing of FOBT kits on overall adherence. The secondary outcomes of this study were the 1-year changes in rates of self-reported test-specific adherence to screening guidelines for FOBT, flexible sigmoidoscopy, colonoscopy, and barium enema x-ray.

### Statistical Methods

All estimates of adherence rates, changes in adherence rates, and differences in changes in adherence rates were adjusted for participant nonresponse and unknown eligibility, and all 95% confidence intervals (CIs) were computed by bootstrapping those estimates. Evaluation of the interventions was based on the estimated rate of reported overall adherence to colorectal cancer screening recommendations and for specific adherence to any of the tests under the guidelines. The change in estimated adherence rate was calculated by subtracting the rate estimated from the responses to the 1-year follow-up questionnaires from the rate estimated from the responses to the baseline questionnaires and then comparing those changes across intervention groups.

**Adjustment for nonresponse and unknown eligibility.** Because participant nonresponse was greater than 10% in all groups and seemed to be associated with several variables thought to be important determinants of adherence, we adjusted, to the extent possible, for self-selection effects, i.e., nonresponse bias. Horvitz and Thompson *(25)* suggested weighting observations by the inverse probability of response to adjust for bias from nonresponse. To implement this approach, we assigned each response from an eligible individual a weight based on the probability of response estimated from a logistic regression analysis on the following predictor variables: county of residence, age, age squared, sex, sex by age interaction, sex by age-squared interaction, driver's license status (current or lapsed), and driver's license address status (deliverable or not).

**Accounting for unknown eligibility in the sample.** The information in the Minnesota State Driver's License and Identification Card database is not entirely accurate. For example, because driver's license renewals are required only every 4–5 years, some individuals who had moved out of Wright County since their previous renewal were listed as being residents of Wright County when the study began. In addition, some birthdates listed in the database are incorrect. Although the eligibility of all but three respondents to the questionnaire was known, the determination of eligibility was unresolved for about 30% of nonrespondents. Hence, to account for unknown eligibility, we estimated the probability of eligibility for each individual of unknown eligibility by using a logistic regression that was based on the same predictor variables that were used for response probabilities as previously described *(26)*. This method also permitted us to estimate the total number of eligible individuals in the sample. The only condition necessary for this method to produce unbiased estimates was that the covariate-specific fraction of eligible participants among individuals with unknown eligibility be proportional to that among those with known eligibility.

**Bootstrap confidence intervals.** The adjusted estimates were computed from estimated weights, so each weight had its own variability. Standard formulae yield asymptotic confidence intervals that are too narrow because they represent only sampling variability and do not address variability from weights. Because of the intractability of deriving exact expressions for the variance of the adjusted estimates, we based our 95% CIs for adherence rates and differences in rates on 2000 bootstrap samples *(27)*. Each bootstrap sample was drawn with replacement from the entire cohort of respondents. Each response was weighted by the estimated probability of response, which was adjusted for subject eligibility. The entire estimation procedure, including estimation of eligibility fractions and response probabilities, was performed on each bootstrap sample to directly incorporate the uncertainty of the estimates of the probabilities of nonresponse and of eligibility into the confidence intervals, along with the usual sampling error, without depending heavily on parametric assumptions. The result was a broader, more robust representation of the uncertainty in the estimated effects that included uncertainty about nonresponse bias, eligibility, and the adjustment for it. Data analysis was performed on the dataset current as of November 14, 2001.

## RESULTS

### Characteristics and Response Rates by Intervention Group

Table 1 shows response rates, age, sex, marital status, educational level, and income by intervention group. At baseline, 1398 individuals were known to be eligible because of their responses to the questionnaire or through tracing their location and vital status. After correcting for unknown eligibility, we found the estimated total number of eligible individuals to be 1451. At the 1-year follow-up, the number of eligible survivors was estimated to be 1395. The response rate for the baseline questionnaire among participants known to be eligible was 89.9%, and the estimated response rate among all eligible participants was 86.5%. Women formed a slight majority overall. The mean age ($\pm$ standard deviation) of all respondents at baseline was 63 years ($\pm$10.2). The estimated percentages of respondents who were married, earned less than $15 000 per year, or had a college education were relatively stable from baseline to the 1-year follow-up.

### Self-Reported Rates of Adherence to Colorectal Cancer Screening Guidelines

Table 2 shows the screening test adherence rates and 95% CIs, adjusted for participant nonresponse and unknown eligibility, for all participants and by age and sex. Older respondents (i.e., those $\geq$65 years old) had higher self-reported adherence rates than did younger respondents (i.e., those $<$65 years old). Older men reported higher rates of adherence to recommended screening test intervals than did older women for endoscopy (flexible sigmoidoscopy [36.5% versus 40.2%] and colonoscopy [32.1% versus 41.9%]); women reported higher rates of adherence to the recommended interval for FOBT than did men at both baseline and at the 1-year follow-up.

### Intervention Effects

Figure 1 plots the adjusted, self-reported screening adherence rates at baseline and 1 year after the baseline survey by intervention group, and Fig. 2 plots the 1-year changes in screening adherence rates and bootstrap 95% confidence intervals by intervention group for all four tests and for overall adherence. The largest changes in self-reported colorectal cancer screening test guideline adherence rates from baseline to the 1-year follow-up were for FOBT; more modest changes were observed in reported overall adherence (adherence to the guidelines for at least one of the four recommended tests). The 1-year rate changes for self-reported adherence to FOBT use were 1.5% (95% CI = –2.9% to 5.9%) for the control group, 16.9% (95% CI = 11.5% to 22.3%) for the group receiving direct mail FOBT with no

**Table 1.** Response rates and characteristics of respondents to the baseline and 1-year questionnaires*

| | Intervention group | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Controls | | Direct-mail FOBT with no reminders | | Direct-mail FOBT with reminders | | Total sample | |
| Rate or characteristic | Baseline | Year 1 | Baseline | Year 1 | Baseline | Year 1 | Baseline | Year 1 |
| No. selected from database† | 648 | 648 | 648 | 648 | 647 | 647 | 1943 | 1943 |
| No. known eligible participants | 464 | 435 | 473 | 426 | 461 | 390 | 1398 | 1251 |
| Estimated no. eligible participants‡ | 482.7 | 468.3 | 487.7 | 468.2 | 480.6 | 458.9 | 1451.0 | 1395.4 |
| No. eligible respondents | 417 | 403 | 434 | 390 | 404 | 351 | 1255 | 1144 |
| Raw response rate§ | 89.9% | 92.6% | 91.8% | 91.5% | 87.6% | 90.0% | 89.8% | 91.4% |
| Estimated response rate‖ | 86.4% | 86.1% | 89.0% | 83.3% | 84.1% | 76.5% | 86.5% | 82.0% |
| Female, %** | 51.8% | 53.3% | 52.5% | 53.6% | 55.9% | 56.4% | 53.4% | 54.4% |
| Mean age, y (SD)** | 63.3 (10.2) | 63.4 (10.2) | 63.1 (10.3) | 62.6 (10.0) | 64.0 (10.3) | 63.2 (9.8) | 63.4 (10.2) | 63.1 (10.0) |
| Married, %** | 78.9% | 77.8% | 80.8% | 79.1% | 77.7% | 78.1% | 73.7% | 78.4% |
| College grad or higher, %** | 15.6% | 13.0% | 15.9% | 13.9% | 16.1% | 15.7% | 15.9% | 14.2% |
| Income <$15,000, %** | 15.2% | 15.0% | 14.3% | 18.6% | 15.0% | 16.3% | 14.8% | 16.6% |

*FOBT = fecal occult blood test, SD = standard deviation.
†Randomly selected from the Minnesota State Driver's License and Identification Card database.
‡Based on estimated probability of eligibility among participants with unknown eligibility.
§Ratio of eligible respondents to known eligible members of the sample.
‖Ratio of eligible respondents to the total estimated eligible in the sample.
**Based on all eligible respondents unweighted for nonresponse.

reminders, and 23.2% (95% CI = 17.2% to 29.3%) for the group receiving direct mail FOBT with reminders. The 1-year rate changes for self-reported adherence to any colorectal cancer screening test were 7.8% (95% CI = 3.2% to 12.0%) for the control group, 13.2% (95% CI = 8.4% to 18.2%) for the group receiving direct mail FOBT with no reminders, and 14.1% (95% CI = 9.1% to 19.1%) for the group receiving direct mail FOBT with reminders.

Figure 3 shows the estimated adjusted differences in adherence rate changes (with associated bootstrap 95% CIs) from baseline to the 1-year follow-up for the combined direct-mail-FOBT groups versus the control group and for the direct-mail-FOBT-with-reminders group versus the direct-mail-FOBT-without-reminders group and shows that statistically significant increases in FOBT adherence and overall adherence (i.e., adherence to any of the recommended tests)

**Table 2.** Self-reported screening test adherence rates from the baseline and 1-year questionnaires*

| | | | Baseline rate | 1-year rate |
|---|---|---|---|---|
| Respondents | Age | Test | Estimate (95% CI) | Estimate (95% CI) |
| Total sample | All | FOBT | 0.214 (0.192 to 0.238) | 0.349 (0.322 to 0.375) |
| | | Flex sig | 0.340 (0.315 to 0.365) | 0.365 (0.338 to 0.392) |
| | | C'scopy | 0.271 (0.246 to 0.296) | 0.313 (0.287 to 0.339) |
| | | BE | 0.144 (0.125 to 0.165) | 0.134 (0.115 to 0.154) |
| | | Overall adherence† | 0.558 (0.531 to 0.586) | 0.674 (0.647 to 0.700) |
| Women | <65 years | FOBT | 0.202 (0.163 to 0.243) | 0.346 (0.299 to 0.393) |
| | | Flex sig | 0.318 (0.272 to 0.364) | 0.338 (0.292 to 0.385) |
| | | C'scopy | 0.187 (0.150 to 0.226) | 0.251 (0.209 to 0.296) |
| | | BE | 0.098 (0.071 to 0.127) | 0.107 (0.078 to 0.137) |
| | | Overall adherence | 0.528 (0.479 to 0.577) | 0.663 (0.616 to 0.709) |
| | ≥65 years | FOBT | 0.282 (0.229 to 0.336) | 0.391 (0.329 to 0.450) |
| | | Flex sig | 0.365 (0.307 to 0.425) | 0.363 (0.302 to 0.426) |
| | | C'scopy | 0.321 (0.263 to 0.380) | 0.349 (0.288 to 0.410) |
| | | BE | 0.185 (0.136 to 0.237) | 0.158 (0.115 to 0.208) |
| | | Overall adherence | 0.613 (0.555 to 0.672) | 0.690 (0.629 to 0.750) |
| Men | <65 years | FOBT | 0.168 (0.132 to 0.207) | 0.300 (0.253 to 0.347) |
| | | Flex sig | 0.312 (0.265 to 0.360) | 0.350 (0.297 to 0.402) |
| | | C'scopy | 0.246 (0.201 to 0.292) | 0.254 (0.208 to 0.300) |
| | | BE | 0.147 (0.113 to 0.185) | 0.122 (0.091 to 0.157) |
| | | Overall adherence | 0.515 (0.464 to 0.567) | 0.633 (0.581 to 0.683) |
| | ≥65 years | FOBT | 0.239 (0.185 to 0.300) | 0.398 (0.325 to 0.471) |
| | | Flex sig | 0.402 (0.336 to 0.469) | 0.456 (0.379 to 0.533) |
| | | C'scopy | 0.419 (0.347 to 0.489) | 0.522 (0.449 to 0.599) |
| | | BE | 0.177 (0.126 to 0.230) | 0.183 (0.127 to 0.243) |
| | | Overall adherence | 0.627 (0.559 to 0.697) | 0.759 (0.692 to 0.822) |

*FOBT = fecal occult blood test, Flex sig = flexible sigmoidoscopy, C'scopy = colonoscopy, BE = barium enema x-ray, CI = confidence interval.
†Adherence to at least one of the four recommended screening tests.

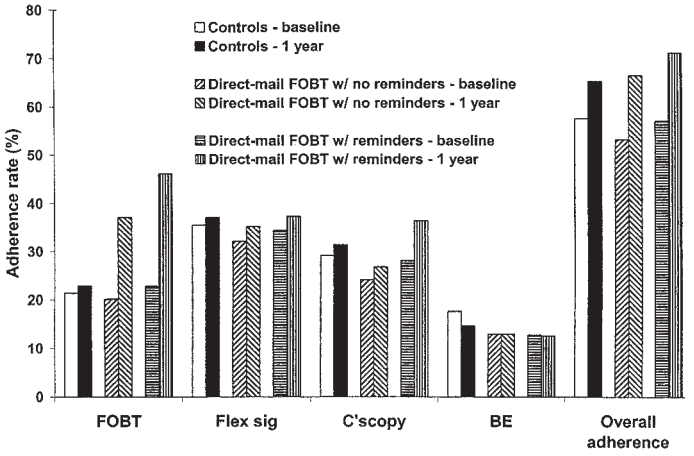


**Fig. 1.** Baseline and 1-year adherence rates by intervention group for each of four colorectal cancer screening test procedures (fecal occult blood test within the previous year [FOBT], flexible sigmoidoscopy within the previous 5 years [Flex sig], colonoscopy within the previous 10 years [C'scopy], barium enema x-ray within the previous 5 years [BE]) and for at least one of the preceding procedures (Overall adherence). All rates are adjusted for nonresponse in a manner that accounts for unknown eligibility.

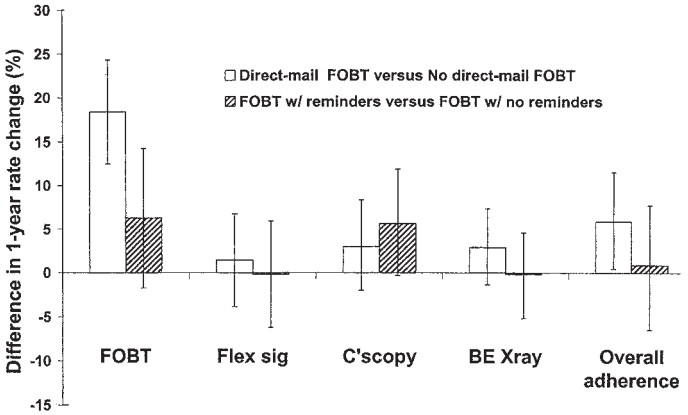


**Fig. 3.** Orthogonal contrasts (differences) in 1-year adherence rate changes and 95% bootstrap confidence intervals (**error bars**) for the combined direct-mail-FOBT groups versus the no-direct-mail-FOBT (control) group and for direct-mail-FOBT-with-reminders group versus the direct-mail-FOBT-without-reminders group for each of four colorectal cancer screening test procedures (fecal occult blood test within the previous year [FOBT], flexible sigmoidoscopy within the previous 5 years [Flex sig], colonoscopy within the previous 10 years [C'scopy], barium enema x-ray within the previous 5 years [BE Xray]) and for at least one of the preceding procedures (Overall adherence). All differences are adjusted for nonresponse in a manner that accounts for unknown eligibility.

occurred for the combined direct mail groups versus the control group. Self-reported adherence to guidelines for FOBT increased 18.4% more (95% CI = 12.5% to 24.3%) in the direct mail group than in the control group; overall self-reported adherence to guidelines for any of the colorectal cancer screening tests increased 5.9% more (95% CI = 0.5% to 11.5%) in the direct mail group than in the control group. By contrast, the differences in the 1-year rate change between the FOBT-with-reminders group versus the FOBT-with-no-reminders group were smaller and not statistically significant. The change in reported FOBT adherence was 6.3% higher (95% CI = –1.7% to 14.3%) for the FOBT-with-reminders group than for the FOBT-with-no-reminders group. The change in overall adherence was only 0.9% higher (95% CI = –6.4% to 7.7%) for the FOBT-with-reminders group than for the FOBT-with-no-reminders group.

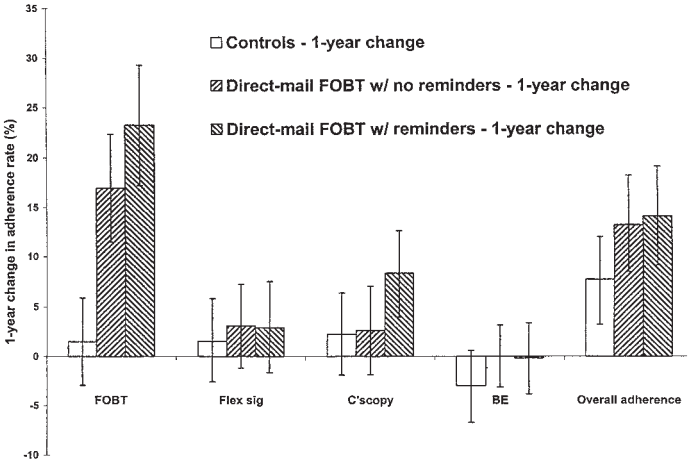


**Fig. 2.** One-year changes in adherence rates and 95% bootstrap confidence intervals (**error bars**) by intervention group for each of the four colorectal cancer screening test procedures (fecal occult blood test within the previous year [FOBT], flexible sigmoidoscopy within the previous 5 years [Flex sig], colonoscopy within the previous 10 years [C'scopy], barium enema x-ray within the previous 5 years [BE]) and for at least one of the preceding procedures (Overall adherence). All changes are adjusted for nonresponse in a manner that accounts for unknown eligibility.

The effects of the interventions, as measured by the 1-year change in adherence rates, varied somewhat with the age and sex of the participant (Table 3). The pooled direct mail interventions led to a modest, but not statistically significant, 4.1% increase in overall reported adherence change for women younger than 65 years compared with a 10.5% increase in adherence change for men 65 years old or older. The effect of the direct mail intervention on reported change in FOBT adherence, however, ranged from 16.3% to 17.4% increases for all strata except older men, for whom the increase in adherence change was 28.2% (95% CI = 13.5% to 43.9%). Among women who were 65 years old or older, those in the direct mail FOBT groups showed a greater increase in reported adherence to colonoscopy (14.3%, 95% CI = 1.1% to 27.3%) and barium enema x-ray (11.2%, 95% CI = 0.5% to 22.1%) than those in the control group. However, these older women in the control group showed a 6.8% (95% CI = –17.4% to 3.8%) decrease from baseline to 1 year for adherence to colonoscopy and a 10.3% (95% CI = –19.8% to –1.6%) decrease for adherence to barium enema x-ray; by contrast, the older women in the direct mail FOBT group showed increases of 7.5% (95% CI = –0.0% to 15.0%) and 0.9% (95% CI = –5.3% to 7.2%) in these adherence rates, respectively.

None of the estimated effects of the direct mail intervention reminder on adherence was statistically significant (Table 4); these comparisons had the least power because of the smaller sample size. Comparing rates among participants who were younger than 65 years and received the reminders with those among participants the same age who received no reminders, we found that the change in overall adherence from baseline to the 1-year follow-up was larger by 0.1% (95% CI = –11.1% to 11.3%) among women and was smaller by 6.7% (95% CI = –19.2% to 6.3%) among men. Among participants who were 65

**Table 3.** One-year change and differences in change in self-reported colorectal cancer screening adherence rates among all participants who received direct-mailed FOBT kits versus those who did not (control group)*

| | 1-year change among direct mail group, % | 1-year change among control group, % | Difference† (95% CI), % | 1-year change among direct mail group, % | 1-year change among control group, % | Difference† (95% CI), % |
|---|---|---|---|---|---|---|
| | | ***Women <65 years old*** | | | ***Women ≥65 years old*** | |
| FOBT | 19.9 | 3.6 | 16.3 (6.0 to 26.8) | 17.1 | −0.1 | 17.2 (2.8 to 30.7) |
| Flex sig | 3.2 | −0.6 | 3.8 (−4.1 to 12.3) | −2.6 | 5.1 | −7.7 (−20.2 to 5.2) |
| C'scopy | 6.9 | 5.1 | 1.8 (−5.8 to 9.3) | 7.5 | −6.8 | 14.3 (1.1 to 27.3) |
| BE | 1.0 | 0.6 | 0.4 (−6.6 to 6.9) | 0.9 | −10.3 | 11.2 (0.5 to 22.1) |
| Overall adherence‡ | 14.8 | 10.7 | 4.1 (−5.6 to 13.0) | 10.6 | 2.2 | 8.4 (−5.2 to 21.6) |
| | | ***Men <65 years old*** | | | ***Men ≥65 years old*** | |
| FOBT | 19.3 | 1.9 | 17.4 (6.3 to 28.1) | 26.3 | −1.9 | 28.2 (13.5 to 43.9) |
| Flex sig | 4.0 | 3.4 | 0.6 (−8.6 to 9.9) | 9.8 | −2.4 | 12.2 (−1.6 to 26.5) |
| C'scopy | 0.0 | 2.1 | −2.1 (−11.5 to 7.2) | 11.4 | 8.1 | 3.4 (−9.6 to 16.1) |
| BE | −3.6 | −0.4 | −3.3 (−10.8 to 4.2) | 4.2 | −6.2 | 10.3 (−2.8 to 23.5) |
| Overall adherence‡ | 13.4 | 8.9 | 4.5 (−5.7 to 15.1) | 16.8 | 6.3 | 10.5 (−3.3 to 24.6) |

*FOBT = fecal occult blood test, Flex sig = flexible sigmoidoscopy, C'scopy = colonoscopy, BE = barium enema x-ray, CI = confidence interval.
†Difference is rounded after subtraction at full precision and so may vary from column differences by a single digit in the last decimal place.
‡Overall adherence = adherence to at least one screening test according to guidelines.

years old or older and received the reminders, overall adherence change was higher by 7.1% (95% CI = –9.7% to 23.3%) among women and by 11.5% (95% CI = –4.6% to 28.0%) among men compared with the change among those who received no reminders. Similarly, for FOBT, comparing rates among participants who were younger than 65 years and received the reminders with those among participants the same age who received no reminders, we found that the change in FOBT adherence rate from baseline to the 1-year follow-up was larger by 5% (95% CI = –9.1% to 19.3%) among women and was smaller by 5.2% (95% CI = –19.9% to 8.6%) among men. Among participants who were 65 years old or older and received the reminders, FOBT adherence change was higher by 17.5% (95% CI = –0.5% to 35.6%) among women and by 18.0% (95% CI = –2.2% to 38.0%) among men compared with the change among those who received no reminders. Again, none of the reminder effects was statistically significant.

## DISCUSSION

This trial demonstrated the potential for a simple, direct-mail intervention to increase the use of screening tests for colorectal cancer in general populations. This trial did not fully address the role of reminders in increasing test use because of disproportionate contamination of one randomization group. Most interventions to increase colorectal cancer screening have targeted clinical systems (e.g., managed-care medical practices and provider networks), individual physicians, or specific patient populations. Although most intervention studies have focused on the use of FOBT, a few have addressed the use of flexible sigmoidoscopy or other methods of screening *(28–38)*. Two intervention studies have been conducted at subjects' worksites *(39,40)*, and one study *(41)* used elderly educators to increase screening among people attending a presentation at a meal. Community-based studies in two areas of France achieved participation rates (defined as completion of at least one screening test) of up to 68.7% through the combined efforts of primary care physicians and public health representatives *(42–44)*. Except for the media campaigns, no community-based interventions to increase colorectal cancer screening have been conducted in the United States.

The county-wide cancer screening initiative that formed the background for our direct mail intervention effort was intended

**Table 4.** One-year change and differences in change in self-reported colorectal cancer screening test rates among participants who received direct-mailed FOBT kits with reminders versus those who received direct-mailed FOBT kits with no reminders*

| | 1-year change among reminder group, % | 1-year change among no-reminder group, % | Difference† (95% CI), % | 1-year change among reminder group, % | 1-year change among no-reminder group, % | Difference† (95% CI), % |
|---|---|---|---|---|---|---|
| | | ***Women <65 years old*** | | | ***Women ≥65 years old*** | |
| FOBT | 22.6 | 17.6 | 5.0 (−9.0 to 19.3) | 25.5 | 8.0 | 17.5 (−0.5 to 35.6) |
| Flex sig | 5.3 | 1.3 | 4.0 (−4.9 to 12.9) | −2.5 | −2.4 | −0.1 (−16.3 to 15.1) |
| C'scopy | 10.5 | 3.9 | 6.6 (−2.6 to 15.8) | 9.7 | 5.7 | 4.0 (−10.1 to 17.8) |
| BE | 2.1 | 0.0 | 2.1 (−4.9 to 8.8) | −4.5 | 7.1 | −11.7 (−24.4 to 0.8) |
| Overall adherence‡ | 14.8 | 14.7 | 0.1 (−11.1 to 11.3) | 14.2 | 7.1 | 7.1 (−9.7 to 23.3) |
| | | ***Men <65 years old*** | | | ***Men ≥65 years old*** | |
| FOBT | 16.5 | 21.6 | −5.2 (−19.9 to 8.6) | 35.6 | 17.6 | 18.0 (−2.2 to 38.0) |
| Flex sig | 0.7 | 6.7 | −6.0 (−16.0 to 4.5) | 13.7 | 6.6 | 7.1 (−11.2 to 25.9) |
| C'scopy | 1.8 | −1.5 | 3.3 (−7.5 to 14.3) | 16.6 | 6.6 | 10.1 (−5.5 to 26.4) |
| BE | −1.4 | −5.5 | 4.2 (−3.9 to 12.9) | 5.9 | 2.6 | 3.4 (−12.1 to 18.7) |
| Overall adherence‡ | 9.7 | 16.5 | −6.7 (−19.2 to 6.3) | 22.8 | 11.3 | 11.5 (−4.6 to 28.0) |

*FOBT = fecal occult blood test, Flex sig = flexible sigmoidoscopy, C'scopy = colonoscopy, BE = barium enema x-ray, CI = confidence interval.
†Difference is rounded after subtraction at full precision and so may vary from column differences by a single digit in the last decimal place.
‡Overall adherence = adherence to at least one screening test according to guidelines.

to combine many of the elements predicted by multiple theories and shown in other screening promotion research to have some beneficial effect on colorectal cancer screening rates. The county-wide initiative attempted to use the sociocultural environment to influence county residents' attitudes by focusing media attention on colorectal cancer screening and by making no- or low-cost screening methods available. These efforts attempted to affect both knowledge and values about colorectal cancer screening. The county-wide initiative also attempted to influence social beliefs about desirable behavior by targeting the community's perceptions about colorectal cancer screening, as well as to motivate individuals to comply with colorectal cancer screening guidelines. Over and above this initiative, the direct mail FOBT intervention was, first of all, an attempt to lower the physical barriers to screening by giving the participant the complete means for obtaining colorectal cancer screening without further cost or requirements other than supplying the test samples and mailing the slides. In addition, the direct mail FOBT kits provided an impetus for a discussion between participants and their health care providers about the topic of colorectal cancer screening. Results of previous research on breast cancer screening *(45)* have suggested that the most potent way to promote any kind of cancer screening is to have the primary health care provider recommend it. The first of these two theoretical effects (namely, lowering the physical barriers) appears to be manifest in that FOBT adherence increased statistically significantly more in the direct mail FOBT groups than in the control group during the intervention period. The second theoretical effect (namely, the prompting of a discussion with a health care provider) may also have played a role, as suggested by the observed increase in use of colonoscopy by the direct-mail-with-follow-up group; although the difference was not statistically significant, the change in adherence to colonoscopy in the direct-mail-plus-reminders arm was about 6% higher than that in the control arm.

A handful of studies have evaluated adherence observed after direct mailing of FOBT kits to individuals. Several studies in the United Kingdom used patients listed in the General Practitioner Registers *(29,30,33,34).* Intervention variations included letters from health departments, letters from personal physicians, educational letters sent in advance of the FOBT mailing, and letters from a general practitioner requesting an appointment or extending an invitation to pick up an FOBT. The adherence rates associated with these interventions ranged from 20% to 60% but were generally less than 50%. One study from Australia achieved an FOBT adherence rate of 60% by using an intervention that included a letter from the personal physician and no dietary restrictions *(46).* In two U.S. studies of patients at health maintenance organizations, Myers et al. *(31,32)* found that an intervention that included an advance letter and a mailed FOBT kit followed by a reminder letter 2 weeks later achieved adherence rates of 27%–29%. Adding further motivational or informational material increased the adherence rate. Elwood et al. *(47)* reported a 15% adherence rate among American Association of Retired Persons members who were sent an FOBT kit. An Israeli study among a population of older persons that used a return-stamped card with a request for an FOBT kit reported an adherence rate of 19% *(48).*

Factors related to nonparticipation in colorectal cancer screening identified in previous studies include pragmatic reasons, such as scheduling difficulties; access issues, such as cost or lack of health insurance; and personal knowledge, attitudes, and beliefs, such as lack of interest, concerns that the test would be embarrassing or unpleasant, a lack of current symptoms or health problems, and a desire not to know about colorectal cancer–related health problems *(48).* Reasons for nonparticipation that are specific to sigmoidoscopy and colonoscopy are concerns about the pain or discomfort associated with the procedure as well as the previously mentioned absence of current health problems, pragmatic reasons, or lack of desire to know about potential health problems.

The combined impact of the direct-mail FOBT kits and active follow-up with reminder letters and calls can be estimated by comparing the 7.7% 1-year increase in overall adherence reported by the control group that received no direct mail FOBT kits (or reminders) with the 14.1% 1-year increase in adherence reported by the group that received direct mail FOBT kits with reminders. This difference of 6.4% in the 1-year rate of increase in reported screening adherence reflects nearly a doubling of the rate of increase compared with that of the control group and suggests that this direct mail effect is a crucial step in overcoming the barriers to screening. Although an increase of 6.4% may seem modest at first glance, the population to which it applies is large. According to the U.S. Bureau of the Census (http://factfinder.census.gov; last accessed January 12, 2004) data for the year 2000, approximately 62 million (80%) of the 77 million total population aged 50 years or older were white and non-Hispanic, like almost all of the study population. If we assume that approximately half of those individuals live in nonurban areas, a 6.4% increase translates into nearly 2 million additional people adherent to screening recommendations.

Although our study was not designed to ascertain the cost-effectiveness of direct mailing of the FOBT kits or the reminders, we estimated the incremental cost of such an effort, focusing on the process of purchasing and mailing FOBT kits and sending reminders. This estimate excluded the cost of tracking the receipt of the kit and developing it, the cost of recording and communicating the results of the test to the participant and primary care provider, and all costs associated with the consequences of a positive or negative result. The incremental cost for the direct mail intervention without reminders was approximately $1351, or approximately $2.80 per individual (482 participants, some of whom were subsequently found to be ineligible, were initially mailed kits). Direct mail with reminders entailed an additional cost of $1849, or about $3.63 per individual (based on the 509 participants believed to be eligible at baseline). The intervention with reminders cost more than twice that with no reminders.

We designed our study to allow us to independently estimate the incremental effects of the direct mail intervention and of the active follow-up of direct mail reminders. The 1-year change in overall adherence for the group that received direct mailing of FOBT kits with no reminder was 13.2%, which was only 0.9% lower than that for the group that received the FOBT kits with reminders. This lack of effect for reminders seemingly contradicts previous research findings on screening promotion *(31,32)* and may partly reflect the fact that approximately half of the no-reminder group inadvertently received a single follow-up letter. However, even double the observed overall effect of reminders is modest. In addition, the group that received FOBT kits with reminders showed a 6.3% greater increase in the rate of adherence to FOBT than the group that received FOBT kits

without reminders (23.2% versus 16.9%, respectively) and a 5.7% greater increase in use of colonoscopy (2.6% versus 8.3%, respectively). Although these increases were not statistically significant, they are consistent in direction with increases reported in other studies *(31,32)*. These results suggest that reminders may increase test-specific adherence while still having a negligible effect on overall adherence because the increases occur among individuals who are already adhering to screening guidelines.

Only the intervention effects on FOBT adherence were large enough to show consistent, statistically significant differences within all age–sex strata. Within each stratum, the effect of direct mailing of FOBT kits ranged from a 16%–17% increase in FOBT adherence except among older men, for whom the increase was 28%. Thus, a direct mail strategy to increase adherence to FOBT screening guidelines may be most efficacious for older men. However, our study was not powered to detect such interactions among strata, and no firm conclusions can be drawn from these results.

The only other statistically significant age- and sex-specific effects were among women aged 65 or older who received FOBT kits via direct mail; they experienced a 14% increase in colonoscopy adherence change and an 11% increase in barium enema x-ray adherence change compared with their counterparts in the control group.

Several limitations of our study merit discussion. First, the primary outcome was based on self-reports of screening behavior, and such self-reported events are subject to respondent error. This error may be exacerbated by the potential for participants to recognize the purpose of the study and be influenced because of the FOBT kit mailing to report positive screening behavior. However, a validity study that compared health maintenance organization records to self-reports from a survey of Colorado residents questioned about colorectal cancer screening (using questions worded similarly to those in our study) *(23)* reported that the estimated sensitivities and specificities of the self-reports for the various screening tests ranged from 88.7% to 96.2% and from 85.9% to 96.8%, respectively. The population in our study is similar to that in the Colorado study in that most Minnesotans are covered by some form of managed care or provider network and tend to be conscious of health care, and they would thus be expected to provide similar responses to such questionnaires. Moreover, nondifferential misclassification errors would not change the overall conclusion that the mailed interventions increase screening compared with no intervention. Because all residents of Wright County were exposed to a county-wide effort to educate them on the value of colorectal cancer screening, respondents might have learned what the "socially desirable" answers to the survey questions were and thus may have artificially increased the reported screening rate. This effect may have been differential because of increased contact between study personnel and the participants who received direct mail FOBT kits. The ability of the respondents to connect the 1-year follow-up questionnaire to the FOBT kit mailings could have led to some differential misreporting, but the high sensitivity and specificity of the questionnaire would limit the bias caused by differential error.

Second, adjustment for nonresponse by stratum-specific weighting of responses may account for bias stemming from the expected differences between those who responded to the survey and those who did not if the strata were defined by all of the factors that affected both response and screening behavior. It is impossible to know for certain that such bias occurred in our study, but the methods we employed adjusted for this to the fullest extent possible, given the information available to the study.

Third, the target population in this study was a nonurban group of predominantly white, non-Hispanic people 50 years old or older. Extrapolating our results to this larger population requires the assumption that groups like this in Minnesota are similar in behavior and motivation to those, for example, in Arkansas, Oregon, or Maine—an untestable assumption within this study. Further, although they represent a sizable fraction of the entire U.S. population, nonwhites, Hispanics, and the residents of urban areas also represent a sizable proportion of the population. Thus, it is even more uncertain whether our findings generalize directly to these populations. However, the principles that underlie the intervention effects are certainly transferable to other populations; the challenge is to discover the appropriate way to implement these principles in the context of those other populations. For example, within minority populations, the direct mail intervention would perhaps need to come from a source that is more trusted by the community than a large research university, such as a medical professional or health group caring for that community. Hence, considerable effort may be required to modify these interventions to make them more appropriate for more diverse or urbanized populations.

Fourth, the contamination due to the erroneous reminder mailing to the FOBT-with-no-reminder group would reduce any effect that reminding may have had on self-reported adherence to screening overall and to FOBT screening specifically. Despite the contamination, there was still a large difference between the two groups in the degree of reminding that occurred. Even so, the intent-to-treat effect estimated here reflects not the pure effect of reminding but rather the incremental effect of applying the three-reminder system to everyone versus applying a single early reminder letter to a subset of the nonresponsive participants. We cannot rule out the possibility that the single reminder letter that was sent to the subset of the no-reminder group had a substantial impact on adherence.

Finally, the organized, community-based promotion of colorectal cancer screening in Wright County may have made the study population more amenable to screening than residents of other communities not exposed to such additional efforts would have been. This potential effect raises the possibility that a different (either smaller or larger) effect of direct mailing of FOBT would be seen in communities without such a community-wide screening promotion. Note that most communities have at least some exposure to colorectal cancer screening promotion, through a combination of public health agencies, private cancer or general health organizations, or federal efforts. More intensive community-wide screening promotion efforts than those used in Wright County may make people more ready to respond to mailed FOBT kits, thus increasing the effect of the intervention, or such promotion efforts may encourage those who would otherwise be susceptible to mailed FOBT kits to be screened disproportionately, thus reducing the intervention effect relative to that observed in our study. Previously published research regarding mailing of FOBT kits *(31,32)* did not estimate the relative year-to-year change in adherence, as was provided in our study, and so cannot provide insight into how the effect might be modified under different circumstances.

In conclusion, our results suggest that direct mailing of FOBT kits to individuals 50 years old or older can have a substantial impact on the use of the FOBT and on overall colorectal cancer screening rates within a general, nonurban population. Because nearly half the population of the United States lives in nonurban settings, our results also suggest that direct mailing of FOBT kits can be used to effect a change in the screening behavior of a large number of people who could benefit from regular colorectal cancer screening.

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## NOTES

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